

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

7 JO HUSKEY AND ALLEN HUSKEY, :
8 Plaintiffs, : CASE NUMBER
9 v. : 2:12-cv-05201
10 ETHICON, INC., ET AL., :
11 Defendants. :

14 TRANSCRIPT OF TRIAL - DAY TWO
15 AUGUST 25, 2014
16 BEFORE THE HONORABLE **JOSEPH R. GOODWIN**,
17 UNITED STATES DISTRICT JUDGE

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1 PROCEEDINGS had before The Honorable Joseph R. Goodwin,
2 Judge, United States District Court, Southern District of West
3 Virginia, in Charleston, West Virginia, on August 25, 2014, at
4 9:08 a.m., as follows:

5 (The jury entered the courtroom at 9:08 a.m.)

6 THE COURT: Good morning.

7 THE DEPUTY CLERK: The matter before the Court is *Jo*
8 *Huskey, et al. versus Ethicon, Inc., et al.*, Civil Action
9 Number 2:12-cv-5201.

10 THE COURT: Are the plaintiffs ready to proceed?

11 MR. WALLACE: Yes, we are, Your Honor.

12 THE COURT: Defendants ready to proceed?

13 MS. JONES: We are, Your Honor.

14 THE COURT: Ladies and gentlemen of the jury, I
15 apologize for the late start. I can tell you it wasn't my
16 fault. It won't happen again.

17 I trust you had a nice weekend. We're now ready to
18 begin the trial of this case. As I mentioned on Friday, it
19 will begin with an opening statement by the plaintiffs, then
20 response to that by the defendants.

21 After that, the plaintiffs, since they have the
22 burden of proof, will put on their evidence. After that, the
23 defendants may put on their evidence. After that, plaintiffs
24 may have rebuttal. And after that, the lawyers will argue
25 their case. And I'll give you instructions on the law, and

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1 then you'll deliberate and decide the case.

2 The important thing to remember is keep an open mind
3 throughout the process. Do not make up your mind until you've
4 heard all of the evidence and my instructions on the law.
5 Opening statements are meant to be a roadmap or a guide as to
6 what each side expects the evidence to prove. Lawyers are
7 always tempted to try to argue their case a little bit in
8 their opening statement. That's not proper. If there's an
9 objection, then there's argument, I'll simply sustain the
10 objection, you ignore that part.

11 Are you ready? You can bring your bottle of water,
12 if you haven't already, and feel free to do that. If you need
13 a break at any time before our normal 10:30 break, hold up
14 your hand and we'll take a five-minute break.

15 Are the parties ready?

16 MR. WALLACE: Yes, Your Honor.

17 THE COURT: All right. Who will open for the
18 plaintiff?

19 MR. WALLACE: Edward Wallace, Your Honor.

20 THE COURT: All right.

21 MR. WALLACE: May I proceed?

22 THE COURT: You may proceed, sir.

23 MR. WALLACE: Thank you.

24 Good morning. I got to meet you on Friday and you're
25 going to get to meet my clients today.

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1 I'm going to get right to it. That's Jo and Allen
2 Huskey right there. Jo and Allen, could you stand up? And
3 you're going to hear from them later on in the trial.

4 And this is my chance to talk to you to outline the
5 evidence, as the judge just discussed. What I'm going to be
6 doing, you have monitors in front of you, I've get some photos
7 and some slides and some documents that I'm going to try to
8 use to outline the evidence. There's going to be a lot of
9 medical terminology. Some of you may be very familiar with
10 it; some of you may not. I may mispronounce the names.

11 The good news is that you're going to hear from
12 medical witnesses who will help us explain these issues to
13 you. But I want to try to put all of this in context, so I'm
14 going to be going through some of the slides today. I'm going
15 to be talking to you. I have a board here. My colleague, Tim
16 Jackson, is going to be putting that board up there, and
17 sometimes as I talk, he'll put some information on the board
18 to help you orient some of the dates, because you're going to
19 see a lot of slides here with a lot of dates and a lot of
20 information. And what we want to do is this evidence is going
21 to come out over the course of the trial. And so what we're
22 going to do with the boards is try to sort of help place it in
23 time of where it came, when it comes to the before and after
24 picture. Okay?

25 So I'm going to get started.

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1 The evidence is going to show, ladies and gentlemen,
2 that Jo Huskey, my client, was implanted with a device on
3 February 23, 2011. That's a key date in this case. That
4 device was designed, it was made, and it was sold by Ethicon
5 and Johnson & Johnson, the defendants in this case. There's
6 no dispute about that. The device, as you heard Friday, is
7 called the TVT-O. It stands for "transvaginal obturator," and
8 you're going to hear a lot of information about the obturator
9 space and the transvaginal approach. And I'll explain some of
10 that today, but, again, you're also going to hear from medical
11 witnesses.

12 This device, the TVT-O, was designed and marketed to
13 treat a condition called "stress urinary incontinence."
14 Again, I'm going to talk a little bit about that today. But
15 you'll also hear from medical witnesses about that.

16 Another important fact that you should know right up
17 front, Ethicon and Johnson & Johnson designed this very device
18 so that it would remain inside of a woman's pelvic cavity
19 forever. There's no dispute about that. It's a permanent
20 implant.

21 There are certain fundamental safety principles that
22 apply here that you should be aware of. The first is that a
23 medical device manufacturer must put patient safety first.
24 That's the number one priority. There should be no questions
25 about that, no excuses.

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1 The second is that a medical device manufacturer must
2 make sure that its products are reasonably safe for their
3 intended use.

4 And finally, third, a medical device manufacturer
5 must provide adequate warnings of risk. Those are three
6 safety principles that we're going to talk about today,
7 hopefully, in some order that I can get through.

8 And we allege here, as you can see on the screen,
9 that Ethicon failed to follow these recognized safety
10 principles. The evidence is going to show, ladies and
11 gentlemen, that Ethicon knew about complications, it knew that
12 these complications were serious. In fact, you're going to
13 learn through the evidence that's introduced in this case that
14 Ethicon knew that some of these events were life altering,
15 life altering.

16 You're also going to learn and the evidence will show
17 that Ethicon made a choice not to disclose this information in
18 its instructions for use and not to disclose this information
19 in other ways. And you're going to hear evidence in this
20 case, some of which I'm going to outline today, and you heard
21 Friday about a reasonable company. We allege by failing to
22 disclose, when it knew the complications were serious, it knew
23 the complications were life altering, evidence that you will
24 see, that Ethicon failed to act as a reasonable person or
25 company. That's one of our claims.

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1 And you're going to hear from several witnesses in
2 this case. Some will sit in that witness box and testify
3 under oath. There will also be people that testify by video
4 deposition. Some of you may know what a deposition is. It's
5 when you're sworn under oath to give testimony. Some of that
6 testimony is sometimes recorded. The good news is that you'll
7 be able to watch it right there. We ask that you watch it
8 just as if they were in this courtroom.

9 One other thing that I want to point out. We submit
10 to you that the evidence you're going to see as to the
11 question of whether or not this device was defective is an
12 overwhelming yes. We want to make that as clear as daylight.
13 But as a brief reminder, this is a civil case. And our burden
14 to prove our claims is by a preponderance of the evidence,
15 meaning that we have to prove our claims are more probably
16 true than not true. (Indicating.)

17 Why do I say this? It's pretty simple. Jo Huskey
18 and Allen Huskey have come too far and too long to get
19 anything other than a fair shake and a fair trial. And that
20 goes for both sides, absolutely. But this is the only place
21 and the only chance that Jo and Allen Huskey will be heard.

22 One other thing. There's going to be a lot of
23 medical witnesses. There are no claims, no claims whatsoever,
24 against the doctor that implanted this device. Nor are there
25 any claims by us or by Ethicon in that regard, by the way,

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1 against this doctor. There are also no claims against any
2 other doctor that provided the follow-up care to Jo Huskey.
3 So remember that as you listen to the evidence in this case.

4 Let me go back to the medical condition. That's a
5 slide, a photo, of normal pelvic anatomy, and you'll see there
6 on the right side of the screen in front of you, you'll see
7 the rectum, the back part of the patient, and you'll see in
8 the front of that, the vagina, and right in front of the
9 vagina, you'll see the urethra. What's important is that
10 you're going to see different views of this same anatomy, so
11 I'm trying to help you keep it in context as you sit through
12 the evidence in this case. Right above the urethra sits the
13 bladder, next to the pubic bone.

14 Now, let's talk about SUI for a moment. The most
15 common cause of stress urinary continence -- incontinence is
16 the weakening of some of the tissues and muscles in the
17 pelvis. It can happen with aging, it can happen as a result
18 of childbirth and other causes. It's a relatively common
19 condition. You're going to learn this in this trial, that it
20 affects somewhere around 30 percent of women who have SUI.
21 Some have it more than others. Some have it with just
22 coughing and exercising and sneezing. Some people have it
23 much more severe than that.

24 And when that happens -- let me show you the next
25 slide. That's the effect of SUI. What happens is that the

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1 urethra that I just showed you falls from its proper position
2 and so that the bladder can then begin to leak involuntarily.

3 One thing that's real clear, or should be real clear,
4 hopefully, by the close of this case, and the evidence will
5 show this: Ethicon designed this TVT-O device to support
6 those weak tissues. Ethicon designed this device for women
7 that were postmenopausal, premenopausal, that had leaking
8 tissues. That's what this device was for. That was their
9 market.

10 You have to -- you have to understand as this case
11 goes along that we'll be talking about some embarrassing
12 conditions. Certainly, perhaps embarrassing or uncomfortable
13 for Jo and Allen Huskey and some of us or maybe all of us.
14 And, but it's important that we talk about this stuff because
15 we have to give this case the dignity that it deserves, so
16 when some of us may say something that's embarrassing or you
17 see something that might be uncomfortable, just rest assured
18 we're trying to do the right thing.

19 And it's important for you to know that SUI does not
20 adversely affect the women's health. As I said, it can be
21 embarrassing, absolutely. It can sometimes be uncomfortable.

22 Let's move on and talk about the TVT-O device. What
23 is the TVT Obturator Sling? The TVT-O actually comes in
24 what's called a kit. It has different pieces that are inside
25 of this kit. It actually comes in a box, and I'm going to

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1 show you the box right now because this is what I'm referring
2 to when I talk about the kit. Okay? And I'll get more into
3 it than that. But I want to talk to you about some key pieces
4 that come inside that kit because this is the product.

5 That's a picture of some of the devices that I want
6 to talk about in this case and outline some of the evidence
7 that you're going to see here. You see there's a strip of
8 mesh and what are called trocars which are the surgical
9 devices to deliver the mesh. You see a winged guide. And the
10 evidence, as I said, will show that Mrs. Huskey had this mesh,
11 the TVT-O mesh, put inside of her on February 23, 2011.
12 That's actually what is left in the body to try to treat SUI.

13 These are the trocars in my hand, ladies and
14 gentlemen, that are used to deliver the mesh. What I've got
15 in front of me is the actual mesh, and it's actually just a
16 strip of plastic. It's made out of a product called
17 "polypropylene." Some of you may have heard of polypropylene
18 before. It's just a manmade chemical that's made by an oil
19 and gas company that is processed and then eventually becomes
20 the mesh. It's obviously a little bit more involved than
21 that, but this is really just a polypropylene mesh, and this
22 is what's left behind in the body, without the sheath that is
23 over it.

24 And this is delivered through what's called the
25 transobturator space. I'm going to try to walk through just a

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1 little bit about how this goes in, okay, but, again, you're
2 going to hear from medical witnesses on this.

3 I'll just try to explain. The TVT-O mesh, it's
4 actually inserted underneath the urethra to hold it in its
5 proper place. And to do that, a doctor actually makes a cut
6 in the wall of the vagina and actually inserts the mesh
7 transvaginally, so that's part of the reason why it's called
8 the "TVT." It sort of means what it says, the O stands for
9 "obturator" because this mesh eventually goes into the
10 obturator foramen and out through the inner thigh and groin.
11 And these trocars are used to push the mesh through tunnels
12 when it goes through transvaginally up through the obturator
13 foramen.

14 Let me just go ahead and get to the slide so maybe we
15 can understand it together. But I want to tell you something
16 before we get there.

17 This obturator space that I've been talking about,
18 again, you're going to hear evidence in this case, this is the
19 testimony of the doctor that tried to take the mesh out of
20 Mrs. Huskey.

21 And there is some testimony from his deposition, it's
22 going to be played by video in this case, and he's asked about
23 his ability to remove the entire mesh.

24 And he's asked, "Can you explain why all of the mesh
25 could not be removed?"

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1 He says he's never done that before. You're going to
2 learn that he's not alone. Operating in the transobturator
3 space is something very few surgeons in the United States, let
4 alone the world, would attempt to do. The implant through the
5 transobturator space is extremely problematic if there is a
6 complication. That's one of our claims in this case. If
7 there's a complication -- remember how I said it was a
8 permanent implant? The evidence is going to show that it's
9 extremely problematic to get this mesh out. The evidence will
10 also show that Ethicon had no prior experiencing -- experience
11 developing an SUI device to be implanted in the transobturator
12 space. That is an important piece of evidence that you should
13 consider in this case.

14 The third piece of the kit, besides the trocars and
15 the mesh, that I want to talk about, are the instructions for
16 use.

17 By the way, before I do that, why don't I just talk a
18 little bit about, that's a better picture of how the TVT-O
19 lays inside the woman's pelvis. If you remember that view
20 that I showed you, I showed you the rectum from the side, on
21 the right-hand side, the vagina and then the urethra, and I
22 said that the TVT-O sits underneath the urethra. This space
23 out here, this here is the obturator foramen and this mesh
24 actually sits in there.

25 That's the obturator membrane that you're going to

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1 hear so much about, and you're going to hear it from people
2 that are much more able to talk about it than I can.

3 But remember, TVT-O means "transvaginal tape
4 obturator."

5 That's actually an animation from Ethicon of how the
6 trocars are used to insert the tape. You can see that the
7 winged guide is being -- the trocars are literally going
8 transvaginally into the obturator foramen and creating these
9 little tunnels, and so the mesh follows along the tunnels
10 which are essentially wounds, and that mesh is supposed to lay
11 there forever.

12 Like I said, the next thing I want to talk about is
13 the instructions for use. That's a piece of information that
14 comes in this kit. Okay? And that tells the physician three
15 important things:

16 It tells the physician how to implant the product,
17 and if you look here you see contraindications. You may have
18 seen that on a label before, on other medical products. It
19 tells the doctor in these kinds of cases who is not an
20 appropriate candidate -- that's going to be very important in
21 this case -- who is and who isn't an appropriate candidate for
22 the TVT-O device.

23 What else is supposed to be in the instructions for
24 use? Evidence you're going to hear in this case, we're going
25 to talk about adverse reactions, risks and warnings. This is

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1 supposed to tell the physician about the complications or
2 adverse events that may be associated with the use of the
3 TVT-O device.

4 And you will learn, and I'll go right to it, you will
5 learn from evidence in this case that Ethicon agrees, Ethicon
6 agrees that the surgeon should be able to solely rely on the
7 IFU, absolutely, to get risks and warnings and information.
8 This is a way that Ethicon can meet its obligation to be a
9 reasonably careful company. And one of our claims is this IFU
10 and this warnings information was inadequate and not provided.

11 This is -- and let me just back up for a second and
12 talk about the fact that, of course, the doctor, once the
13 doctor receives this information, is in the important position
14 of then talking to the patient about the risks. But about the
15 true risks because, as you're going to learn, and you're going
16 to know by the end of this case and the evidence will show,
17 that Ethicon is in the position and has the obligation to know
18 what's going on with its product, and if it knows what's going
19 on with its product, you're going to hear evidence that even
20 Ethicon agrees that it should be in the instructions for use.

21 Right there. That is an Ethicon medical director, a
22 higher-up at Ethicon. His deposition was taken, and he was
23 asked: "Would you agree with me, Dr. Robinson, that the
24 warnings and adverse reactions section should include all
25 significant risks and complications related to the use of the

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1 TTVT?

2 "Well, those deemed significant."

3 And I submit to you that the evidence will show that
4 there were significant complications that were not part of the
5 IFU.

6 He's also asked: "And it should also include risks
7 and complications related to the implementation of the mesh,
8 right?

9 "Well, that's both the device and the procedure,
10 yes."

11 Because this comes in a kit, and as you're going to
12 learn and hear testimony in the case, that this procedure, you
13 can't just do this procedure on a whim. They provide very
14 specific instructions for use that you're supposed to follow.
15 You're going to learn about something called the inside-out
16 approach and other very specific directions, and that are part
17 of the design -- part of the design, ladies and gentlemen,
18 that come with this unique TTVT-O device that raise unique
19 complications. So it's the procedure and the device.

20 Let me talk to you, because you're going to hear
21 information perhaps about other mesh. Let me just give you a
22 brief history lesson.

23 1974, I believe that was when President Nixon was
24 impeached, 40 years ago. The old construction Prolene mesh
25 was developed. 1974. That was not for SUI. That was for a

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1 different application entirely and that was made basically in
2 large sheets. Okay?

3 It wasn't until 1998 that Ethicon got into the market
4 of treating SUI with these mesh sticks, and it made what it
5 called the TVT. Okay? And the TVT, as you see here in 1998
6 and you're going to learn, was inserted much differently. It
7 was also cut much differently than the device that was put in
8 my client. It's a different product, inserted a different
9 way.

10 You're going to learn that in 2003, Ethicon decided
11 to launch the TVT-O with no prior clinical trials. This new
12 way of putting this in, through an entirely new part of the
13 body, where surgeons normally don't even operate. That's what
14 the evidence will show. They decided to launch this device in
15 2003. That device, by the way, in 2003, that first TVT-O
16 device, was cut very much the same way as that 1998 TVT. It
17 was cut mechanically, with a machine.

18 It isn't until 2007 that Ethicon begins what is
19 called laser-cut mesh in the TVT-O. Let me make something
20 absolutely clear when you hear about lots of other different
21 products. The evidence will show that my client received a
22 TVT-O laser-cut mesh which first came to market in 2007. So
23 when you hear about long-term data, keep that date in mind.

24 As you know, she received the TVT-O laser-cut mesh on
25 February 23, 2011. And you're going to hear evidence in this

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1 case that Ethicon had safety signals in front of it, and it
2 failed to stop when it saw those signals, that it moved ahead,
3 that it made decision -- made decisions at the highest levels
4 of the company. The Board of Directors was making decisions
5 about what was going on with this device. So what did Ethicon
6 do wrong?

7 Well, you're going to learn that Ethicon, prior to
8 the TVT-O device, never did a randomized control trial with a
9 primary outcome safety prior to launching. What is a
10 randomized control trial? Some of you may know this. It's a
11 clinical trial that you can use in a controlled clinical
12 setting to assess how your product is performing. But what
13 are called "endpoints," what you're actually looking at in
14 this study, is really important because you can be comparing
15 one product to another and say, "Well, my product works just
16 as good as the other one. But that's not at issue here.
17 Whether my product works as good as the other one is not at
18 issue here.

19 The question is about safety. Are you putting safety
20 first?

21 Again, what did Ethicon do wrong? We allege that
22 Ethicon rushed the TVT-O to market without the proper clinical
23 data, especially safety data. We allege that Ethicon
24 converted from mechanical-cut mesh to laser-cut mesh without
25 any clinical tests or long-term data.

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1 Important claim. Ethicon knew -- we allege that they
2 knew that the TVT-O was causing serious problems for women but
3 did nothing. And we allege that Ethicon did not disclose
4 those complications to doctors and to the public.

5 What is the result? What is the result, ladies and
6 gentlemen? Why is the TVT-O defective? It's the wrong
7 material. You're going to learn about polypropylene in the
8 pelvis. You're going to learn that it was in the wrong space.
9 It was inserted through the obturator space. You're going to
10 learn that it was the wrong approach. It came with unique
11 risks that Ethicon knew about right after this product
12 launched. It was the wrong amount. Too much mesh equals
13 increased complications, and we allege that Ethicon knew about
14 it and sat on this information for years. It was the wrong
15 product.

16 Now, there are lots of other choices out there, and
17 you're going to learn today, as I speak to you, about some of
18 these other choices. And let's -- to do that, let's go back
19 to that first safety principle. A medical device manufacturer
20 must put the safety of patients first. What did we allege?
21 We alleged that Ethicon rushed this product to market.

22 What do I mean by that? Well, in 1998 when Ethicon
23 first began selling this TVT, the evidence is going to show,
24 as you know, that it was a completely different product. What
25 started happening after a few years was that Ethicon was

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1 losing market share. Ethicon, the evidence will show, was
2 losing market share quickly. And Ethicon wanted to do
3 something quickly to change that. They wanted to try to
4 recover that market share.

5 They did do that in the sense that they rushed this
6 product to market in record time to attempt to recover that
7 market share. Right in front of me -- and I'm going to go up
8 to the board so I can actually read it -- this is talking
9 about the TVT-O. This is exhibits -- or an exhibit that
10 you'll see in the case, and it talks about why the TVT-O was
11 actually created.

12 It was created in response to what? That's evidence
13 you should consider. What was it created in response to? It
14 was created in response to the fact that "They're rapidly
15 stealing our TVT retropubic sales at an alarming rate." They
16 originally estimated that the TTVT-O would take 24 months to
17 launch. They did it in nine months, a record for the company.
18 A record for Ethicon.

19 What else? This is other information that you will
20 see in this case. "To protect our market share, we need to be
21 ready to launch. So the development process should not
22 require clinicals. I understand that the Gynecare Board made
23 the decision that clinicals will not be required for
24 Mulberry." That's the TTVT.

25 The Gynecare Board, ladies and gentlemen, this is the

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1 higher-ups at Ethicon that are involved in these decisions,
2 the rationale, the rationale, was to defend their sales. But
3 let me make something very, very clear. I'm not sitting up
4 here complaining that it's wrong to make money. Competing is
5 not wrong. Developing products is not wrong. There's nothing
6 wrong with that. But when you prioritize patient safety, that
7 first safety principle that we talked about, we allege in this
8 case that it was wrong and it had consequences.

9 The evidence will show that Ethicon decided to launch
10 first and worry about problems later. What am I talking
11 about? Let's move on to our next safety principle: "A
12 medical device manufacturer must make sure that its products
13 are reasonably safe." I just told you about the evidence
14 showing that Ethicon would launch first and worry about
15 problems later. You're going to see evidence in this case,
16 remember that timeline that I showed you, that they released
17 in late 2003. In early 2004, March of 2004, there is a secret
18 meeting with the inventor of the TVT-O. Why did they have
19 this meeting? The evidence will show, ladies and gentlemen,
20 that the co- -- the coinventor of the TVT-O met with Ethicon
21 because women were experiencing pain because of this
22 technique, because of this unique TVT-O. They were discussing
23 ways, you're going to learn, in March of 2004, how to modify
24 the TVT-O in an attempt to reduce that pain.

25 That's actually a document, the Professor de Leval is

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1 actually one of the co-inventors of the product, you'll see
2 that's dated March 29, 2004, and what is he talking about?
3 He's talking about reducing the tape. He's talking about
4 removal of the segment of the tape that passes through the
5 adductor muscles. They are concerned at this point about pain
6 that is being caused to women early on after the launch of
7 this device. You will learn that changes like this were not
8 made for years, for over six years.

9 In 2009, two years -- two years, ladies and
10 gentlemen, the evidence is going to show, two years before my
11 client gets implanted with the TVT-O device, there is a
12 meeting with an Ethicon medical director and the co-inventors
13 of the TVT-O, Dr. de Leval and Dr. Waltregny. And at that
14 meeting, they again discuss their concerns. Because of what?
15 This is a memo, a report of this meeting. "That the foreign
16 body reaction of the mesh and the trajectory outside the
17 obturator membrane plays a role in the development of pain."

18 Remember what I said to you about the obturator
19 space. This is a report of a meeting two years before my
20 client was implanted with mesh.

21 The evidence will show that they were still talking
22 about design changes to reduce pain years later and well in
23 advance of my client being implanted with this device.

24 What else is important about this? The second source
25 of pain comes from the presence of tape in the adductors.

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1 This is of specific importance in young, active and/or
2 sportive patients. That's what's going on two years before my
3 client gets this device. The evidence will show that no one,
4 doctors, were not informed of this, of these concerns. The
5 IFU was not updated.

6 And when we're talking about the obturator space,
7 you're going to learn about the foreign body response. I'm
8 just going to switch gears for just a second and talk about
9 the TVT-O and the concerns that they talked about in this
10 obturator membrane where very few surgeons will go, this TVT-O
11 is now reacting to the tissue in that space and the vaginal
12 tissue is now reacting to the polypropylene, causing the
13 problems in patients. That's what the evidence is going to
14 show.

15 This is the deposition testimony of Dr. Gretchen
16 Byrkit, and she's asked about active patients. And you're
17 going to learn that Jo was a physical therapist assistant and
18 was quite active. She went up to eight miles a day on her
19 elliptical. Dr. Byrkit testified in this case. She's going
20 to be seen in this courtroom by video deposition. She's
21 asked: "So as far as the TVT-O is concerned, an active
22 patient, somebody who is, say, a water aerobics instructor or
23 somebody who does physical therapy, were they contraindicated
24 for the TVT-O procedure?

25 "Not to my knowledge."

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1 Remember when I showed you the IFU, which will come
2 into evidence in this case? That was not a contraindication.

3 She's asked: "If you had been told that it shouldn't
4 be implanted in women who are active, actively exercising, fit
5 women, if you had been told that it shouldn't be implanted in
6 those women, would you still have implanted it in Jo Huskey?

7 "I don't think I would."

8 Again, competing is not wrong. But putting patient
9 safety first has to be a priority.

10 Laser-cut mesh, we've talked a little bit about it.
11 You'll see here that, again, this is another attempt to
12 maintain market share. Again, there's nothing with trying to
13 maintain market share. But they decide not to do -- to seek
14 clinical data on it.

15 And this is an e-mail from Allison London Brown, an
16 employee of Ethicon, and she is recommending that they need
17 clinical data on the laser-cut mesh that is put in my client,
18 prior to launch.

19 The evidence will show that this did not happen. No
20 clinical data. And what are they saying about how the
21 laser-cut compares to that mechanical-cut that came out in
22 2003? Inability to claim equivalence. They're ignoring --
23 the evidence will show that they ignored concerns within the
24 company that clinical data was needed before this was
25 launched.

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1 This was the wrong material and the wrong place.
2 Let's talk about a concept called "degradation." I told you a
3 little bit about the foreign body reaction and you saw that
4 never-ending cycle where the polypropylene reacts to the body
5 and the body reacts to the polypropylene. You're going to
6 hear a lot about that. Ethicon found degradation going back
7 to the 1980s. There were researchers that were starting to
8 find degradation in explanted material from patients, 2009,
9 2013.

10 Again, I talked to you about the fact that this is
11 plastic. This is a manmade chemical. You're going to learn
12 that this manmade chemical in the pelvis can break down, it
13 can become brittle, it can curl, it can shape, it can deform.
14 And you're going to -- by the way, you're going to hear that
15 polypropylene is used elsewhere in parts of the body and that
16 it's in sutures and that it's a used in many, many other
17 places in the body.

18 Again, I want to make one thing clear. This case is
19 not about sutures. This case is about mesh, which is many,
20 many, many times more polypropylene than a plain suture.
21 Polypropylene is this -- woven together to form this mesh. It
22 grows into the body quite differently and it's quite a
23 different reaction and you're going to learn about it.

24 And you will hear that experts in the scientific
25 field have long accepted that polypropylene is unstable and

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1 can be brittle.

2 And you're going to hear that degradation,
3 polypropylene can cause this response in the human body. The
4 mesh in the pelvis can incite what is called "chronic
5 inflammation, chronic foreign body reaction and extensive
6 scarring." And it can cause serious issues with pain. These
7 can cause serious problems with women, sometimes called
8 "chronic pain syndrome."

9 Another problem is that when the mesh degrades, it
10 can become brittle, and you're actually going to hear from
11 physicians that try to remove this and as they take it out, it
12 begins to break apart.

13 So if you're going to use mesh, you should really
14 only use it where it's needed, because when you incite more of
15 a foreign body response, the evidence is going to show you're
16 just asking for problems.

17 And you're going to learn, the evidence is going to
18 show, that what was happening, these are -- let me just step
19 over here and just explain this. These were reports from
20 1998, where Ethicon is finding degraded polypropylene. This
21 is medical literature that comes out finally in 2012 that is
22 catching up to what Ethicon knew back then.

23 I just said the word "chronic pain syndrome." You
24 will not find that anywhere in the instructions for use.

25 Piet Hinoul is the medical director, medical

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1 director -- or, in fact, was the chief medical director of
2 Ethicon. And what does he say? He says, on January 7th,
3 2009, earlier in the morning: "I feel that patients after a
4 TVT-O do have more pain than after Monarc." Just a little
5 tidbit here that you should know about. Monarc is a competing
6 device made by a different manufacturer. And that's what he's
7 saying about his device, the TVT-O.

8 He writes, he's personally convinced that after
9 having published some in the vicinity of the nerve branches of
10 the obturator to the tape's trajectory, that the presence of
11 this foreign body will induce more pain and will be
12 responsible for some of the chronic pain syndromes. We submit
13 that this evidence was never disclosed. This is two years,
14 again, before my client's implant.

15 Less mesh equals less complications. You're going to
16 see that, again, Piet Hinoul was acknowledging this in 2010
17 and knew about it years before that, that there were problems
18 with the TVT-O.

19 I don't want to spend too much time on this, but I
20 want to direct your attention, this is an internal company
21 document, talking about leaving less mesh behind. That's an
22 important concept because, as I told you, as Ethicon knew and
23 the evidence will show, the less mesh equals less
24 complications.

25 Look at the words "persistent pain," "chronic pain

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1 syndromes." You will not find that anywhere in the
2 instructions for use.

3 Talks about a key unmet need to the obturator. Don't
4 forget that we're talking about the TVT-O which is in the
5 obturator space.

6 Those are just some of the advantages of less mesh.

7 We talked about it; I'll move on.

8 These are not routine postoperative complications,
9 ladies and gentlemen. So when you hear that the TVT-O carries
10 with it just risks like any other surgery, you're going to
11 hear about some of the other alternatives that are available.
12 There are competitors' devices, which we're not here about, so
13 there are other mesh alternatives that are inserted
14 differently, not the inside-out approach of the obturator
15 membrane, and not with the same kind of mesh that's at issue
16 in this case.

17 You will also learn that there's other non-mesh
18 surgeries available. One is called the autologous fascial
19 sling procedure. Another one is called the Burch procedure.
20 And, of course, we have the TVT-O. Those are just some
21 alternatives.

22 Does the autologous fascial sling cause chronic pain
23 syndrome? No. Does the Burch? No. You'll learn the TVT-O
24 does.

25 Pelvic floor muscle spasm. Autologous fascial sling

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1 and Burch, no. TVT-O, yes. So when you're thinking about the
2 benefits of the TVT-O, this is evidence that you can consider.

3 Sexual impairment due to scarring and contraction of
4 the mesh. Remember that this mesh can shrink and can fold and
5 curl up inside a woman's body where it's supposed to be
6 forever. No with the autologous fascial sling. No with the
7 Burch. The TVT-O, yes.

8 Difficulty removing? TVT-O.

9 You're going to learn, ladies and gentlemen, the
10 evidence in this case, that medicine and science are finally
11 catching up to what Ethicon has known about since at least
12 2004. Perhaps earlier. What am I talking about? This is in
13 2011, 2012 when my client was operated on by Dr. Siddique to
14 try to take the mesh out, and what does he say in his
15 deposition about operating in the obturator space and the
16 difficulty with this surgery?

17 He says, "It's a matter of comfort level and there
18 are places that are developing the comfort level to take those
19 out. I don't know how many" cases -- "centers across the
20 country. I know of one case report that I read" -- I'm not
21 going to read the whole thing to you. You're going to see his
22 video deposition played here.

23 But look at what he says at the end. You're going to
24 learn, he's a very experienced urogynecologist. He says: "I
25 honestly don't know where specifically to send people for

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1 stuff like that." This is the experienced gynecologist that
2 the implanting physician referred my client to in an attempt
3 to solve her complications.

4 Ethicon, in 2004, is talking about the increased
5 pain, the transobturator approach. Literature, you're going
6 to hear a lot about the literature in this case. There's
7 finally now being published literature that speaks about this
8 very issue.

9 Difficulty removing the TVT-O device. Something
10 Ethicon was discussing in the 2000s, all the way up through
11 2009. In 2012, there are now articles that are being
12 published about the obturator foramen dissection and how
13 difficult that is.

14 And remember the knowledge that Ethicon had for years
15 before my client was implanted about putting this TVT-O device
16 in lean and active women? We said this information was not
17 disclosed. And we showed you the testimony from Dr. Byrkit
18 that was on the monitor in front of you. It is only now, in
19 2014, that this is starting to come out.

20 Look at the conclusion of this medical literature:
21 "These findings support previous evidence that leaner women
22 experience greater pain following transobturator mid-urethral
23 slings. Such findings may inform surgical planning and
24 pre-operative counseling."

25 We submit that this is information that any woman

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1 would want to know.

2 And you're going to hear a lot about studies.

3 Go back.

4 And you're going to hear information about randomized
5 controlled trials and what they really mean. You should ask
6 yourself, not only accept what you're told, but what -- what
7 does this really show you? Think about the specifics.

8 Remember when I talked to you about a study comparing one
9 product to another? The issue here is safety. We're not
10 comparing one product to another.

11 You may hear, for example, that mid-urethral slings
12 have been called the gold standard. We're not here about
13 mid-urethral -- all mid-urethral slings. We're here about the
14 TVT-O laser-cut mesh device. And what's important about that
15 is you will not see any evidence of any organization or
16 society ever calling the TVT-O laser-cut mesh the gold
17 standard.

18 Another thing about the gold standard is that it is
19 the preference for what is being used most at that time, and
20 it's typically supported by data. You will hear evidence that
21 the Burch and autologous procedures and perhaps other
22 procedures with mesh were alternatives.

23 What's important here? When you hear evidence about
24 long-term data, remember what I said about the laser-cut mesh.
25 I want you to pay attention to this author here, an

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1 Ethicon-paid researcher. This is an Ethicon-paid researcher,
2 Nilsson, seven-year paper, 11-year paper, 17-year paper. He's
3 talking about the TVT and that data. Please don't forget
4 that.

5 Here's what's also important about this evidence that
6 you're going to see. What does this Ethicon-paid researcher
7 say about laser-cut mesh? "Will not use laser-cut mesh. Does
8 not have the same stretch profile of mechanical-cut mesh."

9 So when you are told about long-term data, remember
10 that the laser-cut mesh came out in 2007. There is no 17-year
11 paper or 11-year paper, and when you see Nilsson's name,
12 remember what he said about laser-cut mesh. That is
13 important, very important evidence for you to consider.

14 This brings us to one of the most important issues in
15 this case and that's the need to disclose. We submit that
16 there's no harm in disclosing, let me know; but there can be
17 plenty of harm in not doing so. In this country, that process
18 in the medical field is called "informed consent." It
19 protects a patient's right to choose his or her medical care.
20 A physician is required to get permission from a patient
21 before that happens. That's a standard of care you're going
22 to hear about in this case, and it's a standard that, frankly,
23 is just based upon as much on good common sense as it is
24 medicine. A doctor and the patient are entitled to know the
25 good and the bad.

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1 The evidence will show in this case that Ethicon is
2 in the best position to know what's going on with its product.
3 It actually has systems that are supposed to -- that are
4 surveillance systems to see how its product is performing and,
5 if necessary, to take action on its product or to update that
6 instructions for use that we've talked about.

7 What are we now learning? The medical community is
8 now reporting serious mesh complications. "Changed women:
9 The long-term impact of vaginal mesh complications." Managing
10 these complications is fraught with complexity.

11 We are now learning about the impact of mesh
12 complications on emotional health. The number of women that
13 are getting referred for complications has increased
14 substantially. You're going to hear about this evidence. So
15 when I talk to you about disclosure, keep what's now happening
16 in mind.

17 And this brings us to the issue of warnings. That's
18 the third safety principle. And what does David Robinson,
19 that medical director, say? He says, "It's important for
20 patient safety that all the significant risks and
21 complications be provided to both doctors and to patients
22 either from doctors or from information from the company."

23 There's the IFU. And I ask that you look at this
24 language. This is what it says: "Transient leg pain lasting
25 24 to 48 hours may occur. It can be usually managed with mild

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1 analgesics." Aspirin, Motrin, Tylenol. "Transitory local
2 irritation at the wound site and transitory foreign body
3 response." Chronic -- "This response could result in
4 extrusion, erosion, fistula formation or inflammation."

5 The IFU, ladies and gentlemen, we would submit, is
6 not supposed to downplay the risks. The words "minimal" and
7 "transient" mean something. "Transient," I see here mentioned
8 four times. That just means "transitory," meaning
9 "short-term." It sends a message.

10 The -- remember that -- the slides that I showed you
11 about degradation? The evidence will show that Ethicon felt
12 it was important enough to put in the IFU that this mesh was
13 not subject to degradation. So if you hear that there's no
14 clinical implications to degradation, you not only can ask and
15 sift the evidence as to what you see, but also what you don't
16 see. You can ask yourself, why is that there?

17 That is Meng Chen, ladies and gentlemen. She's going
18 to testify by video in this case. And she's the safety
19 surveillance director. And what does she say about her
20 experience? Going back to 2009, you're going to learn that
21 there were thousands of complaints that were coming in to
22 Ethicon. Meng Chen was actually fielding phone calls from
23 patients, and what does she say? She says she had
24 conversations with patients that they continued to experience
25 serious life-changing-type pain, serious pain that affected

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1 the quality of their life and their daily activities.

2 What else did she say? She was aware of patient
3 reports where the patient told her that they would have
4 painful intercourse for the rest of their life. She had those
5 discussions.

6 What did she decide to do about it? Well, remember
7 what I said about that word, "transitory," that it was
8 short-term? What did she say to her superiors at Ethicon?
9 This is evidence that you'll see in this case from Meng Chen.
10 She is the Ethicon safety director. I mentioned a few minutes
11 ago about the safety surveillance systems that are supposed to
12 be set up to monitor what's going on in the field and, if
13 appropriate, take action.

14 She takes action and what does she say? "Pardon me
15 again, from what I see each day, these patient experiences are
16 not transitory at all."

17 What does she also do? She recommends from the
18 senior management perspective, again, the higher-ups at
19 Ethicon, "One of the paths for a better preoperative consent,"
20 it's that informed consent that I talked about, "is to provide
21 an updated IFU to the operating physicians reflecting the
22 current knowledge of the manufacturers on the potential
23 adverse reactions."

24 Update the IFU. Remember what I said very early on
25 in this case, when I said that Ethicon knew that there were

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1 serious life-altering events? That's evidence you're going to
2 see, ladies and gentlemen, life-altering events. And I said
3 that Ethicon made a deliberate choice not to disclose and not
4 to update their IFU. You will learn that that IFU that has
5 been in place since this product came out was never updated to
6 reflect the knowledge. That's what the evidence will show,
7 ladies and gentlemen.

8 The failure to disclose makes informed consent
9 impossible. The frequency and severity of complications,
10 chronic pain, difficulty of removal, degradation and
11 hardening. In fact, they say degradation doesn't even occur.

12 Contraction and scarring, excessive scarring comes
13 with mesh. You're going to learn that. We're not -- we're
14 not talking about scarring in the traditional sense. You're
15 going to learn a lot more about that kind of stuff. Informed
16 consent is impossible. That's what the evidence will show.

17 And that affected Jo Huskey. Now, you've already
18 heard and you've had an opportunity to briefly meet, not talk
19 to Jo Huskey yet or hear from her. And I told you that some
20 of this stuff is going to be personal. There's no dispute in
21 this case that she had stress urinary incontinence. There's a
22 record right there from her physician. And she discussed this
23 procedure with her physician, this TTVT-O procedure. And I
24 submit to you that as we go through the evidence in this case
25 and this case unfolds, that there's not a whole lot in

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1 dispute.

2 Her current diagnosis, which should not be in
3 dispute, but the evidence will show, it's pelvic floor
4 myofascial pain and levator muscle spasm.

5 What's in dispute here is whether the TVT-O and the
6 implant surgery and the explant surgeries that she's had were
7 a cause of that levator spasm and whether Ethicon adequately
8 warned Dr. Byrkit.

9 Let's talk just real briefly about Jo's activity
10 level. Jo's activity level was high. You're going to hear
11 that she was on the elliptical for sometimes eight miles at a
12 time. She would walk, she'd walk with her dogs. Her husband
13 and her enjoyed the outdoors, going on vacations. Her
14 activity level has dropped dramatically since the TVT-O was
15 implanted on February 23, 2011.

16 Let's talk about her visit with Dr. Byrkit real
17 quick. Just so we're clear, she gave a full history to
18 Dr. Byrkit. She told her about her prior hysterectomy. She
19 even told her about a tonsillectomy. The evidence will show
20 she told her about an appendectomy and a gallbladder surgery.
21 She told her about prior back pain surgery, said she had
22 indigestion and heartburn.

23 She gave a full history. This is key evidence. Why
24 is it? When we talk about those contraindications, based on
25 the information that Dr. Byrkit had, Jo Huskey was an

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1 appropriate candidate for the TVT-O at that time. And so she
2 was implanted with this mesh on February 23, 2011. It's
3 undisputed that Mrs. Huskey suffered from an exposure through
4 her vaginal wall from the mesh material, that it was literally
5 coming through her vaginal wall. And it caused Jo and Allen
6 Huskey pain with intercourse.

7 Mrs. Huskey and Dr. Byrkit made a decision to do
8 something that's called oversewing in an attempt just to cover
9 up the mesh to see if it would heal. Unfortunately, that
10 operation did not work. The mesh is still visible in the
11 vagina, and Dr. Byrkit recommends more treatment, someone with
12 more expertise in treating these complications.

13 This is a little bit hard to see, but I want you to
14 pay attention to something from this July 15, 2011, visit. I
15 believe that's the last date that Jo saw Dr. Byrkit because
16 Dr. Byrkit refers Jo to Dr. Siddique. What does he say? He
17 says, "At this point her" -- I'm sorry. She says, "At this
18 point Jo was very upset, which I can understand."

19 She goes to Dr. Siddique. She sees -- he sees that
20 there's two centimeters of mesh, that at least he can see that
21 much on examination. What's important? He sees her in
22 August. He also sees her in October. He also sees her, I
23 believe it's October 12th. And what's really important here
24 when you hear the claims in this case, that he did a number of
25 exams on her -- a number.

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1 Let me read off what he found just real quick. He
2 said her bladder wall is normal, no lesions, no polyps. Her
3 mucosa was normal.

4 No viticulose [phonetic] was noted. I'll talk to you
5 about that in a minute.

6 The notes regarding her vagina only mention the mesh.
7 There's no mention of excessive scarring or anything like
8 that.

9 So when you're deciding what caused Jo Huskey's
10 levator spasm, remember Dr. Siddique's examination and some of
11 the other evidence that you're going to hear in this case.
12 Dr. Siddique eventually decides to do surgery. What does he
13 find? He saw two centimeters of mesh when he examined her
14 vaginally. Once he opened her up, he found there was a
15 chronically infected space with woody, edematous tissue. That
16 means swollen tissue. He uses Mayo scissors to literally try
17 to cut this mesh out.

18 I talked to you about the remaining mesh. The
19 remaining mesh went behind the pubic bone and it retracted and
20 it was not digitally palpable. What that means is he could
21 not find that mesh that retracted behind the pubic bone on
22 examination. He talks here about how he tried to remove the
23 mesh.

24 One thing I'd like you to focus on is how he tried to
25 remove the mesh. He tied a silk suture to the mesh and

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1 applied traction. He tried to pull this out of her vaginal
2 tissues. He used the words "downright impossible to remove."
3 What does he say? I used the word "levators" earlier. It's
4 very important in this case when you're considering the
5 evidence. What does Dr. Siddique find? He finds afterwards,
6 pain lateral at levators behind the pubic rami. I want to go
7 back to that operative note. "The mesh retracted behind the
8 pubic rami." I'd ask that you pay particular attention to his
9 description of the pain, where it was, and these records when
10 this evidence comes in in this case.

11 What else did he say about this? This is not his
12 record, this of course, is his deposition. He's asked:

13 "She's experiencing deep pelvic pain?

14 "Yes. She has pain at the levators behind the pubic
15 rami bilaterally. So there's a muscle group that's lateral to
16 the vagina, and when I pressed on that muscle group, she had
17 pain.

18 "And what could that be caused by?

19 "That could be caused by the fact that she had
20 surgery in that area, now for three times."

21 Ladies and gentlemen, that's the levator muscles.
22 Again, I told you this is a very narrow dispute. There is a
23 tender area that -- and "tender" is a gentle description, but
24 there is a tender area right underneath the urethra where the
25 TVT-O goes through. There's also spasm in the levator muscle,

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1 as you can see right there, where the little red mark.

2 So when you -- let me take a step back. I want to
3 mention one other thing about Dr. Siddique's treatment. Jo's
4 pain gets worse after this surgery. And what does
5 Dr. Siddique do? She gets three rounds, three separate times
6 of what are called "levator injections." Levator injections,
7 which are literally shots into her levator muscles in an
8 attempt to stop the pain. Her husband is going to tell you
9 what he saw in that regard.

10 So when you decide whether or not the TVT-O is the
11 cause, you have to look at things like proximity and timing
12 when it comes to the evidence. This includes evidence of the
13 TVT-O implant and the explant surgeries, and you're going to
14 hear that these explant surgeries don't just simply cleanly
15 excise this little area around the TVT-O and neatly take this
16 out. You've already seen testimony from Dr. Siddique about
17 that. They literally have to try to cut this stuff out.

18 That's what the evidence will show.

19 And you can also take into account the evidence that
20 will come in as to the timing of her levator and syndrome
21 diagnosis. There is no evidence in the record that she had
22 levator spasms or any kind of diagnosis like that prior to the
23 TVT-O surgery. You can take that evidence into account.

24 You will hear evidence that the area of this spasm is
25 directly in that area and, at most, is two centimeters away

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1 from where this mesh was placed.

2 Here's one other really, really important fact
3 because this picture does not do the insertion method justice.
4 And I'm going to read this to you. You're going to hear
5 evidence that the TVT-O course directly underneath the levator
6 muscles on its way to the obturator foramen. That's that
7 opening in the hip bone. The levator muscles, ladies and
8 gentlemen, as you learn about the anatomy in this area, attach
9 to the pubic rami.

10 So you remember those records, you remember those --
11 that testimony, and please take that into account as you hear
12 the evidence come in in this case.

13 You will also hear that the levator wall spasm can be
14 felt right through the wall of the vagina where the implant
15 occurred.

16 Now, no one is suggesting that Jo Huskey did not have
17 a prior medical history. She had a prior medical history and
18 you're going to hear about that.

19 But, as I told you before, the evidence is going to
20 show, this TVT-O device was designed for people just like Jo
21 Huskey, who had children, who might have been premenopausal or
22 postmenopausal. The device itself, you will learn and the
23 evidence will show, was made for weakened tissues in the
24 pelvis, designed by Ethicon that way. And you're going to
25 learn that the medical issues that Jo Huskey had were either

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1 well controlled or occurred -- some were more than a decade
2 prior to her implant.

3 What am I talking about? You're going to hear that
4 she had back surgery in 1997 and 2000. But before I get
5 there, let me tell you what her own treating doctor told her
6 before she got the TVT-O. This is a medical record in this
7 case. Her doctor told her she had no chronic disorders.
8 That's evidence that you can consider in this case.

9 Her 2000 back surgery, look at what the doctor says
10 about her 2000 back surgery: "Overall, I think she's doing
11 quite well. She's dramatically better. She's increased her
12 activity appropriately. She's ahead of schedule."

13 She also had something called "sacroiliac joint
14 pain," from time to time. She suffered from sacroiliac joint
15 pain on and off for about ten years prior to the -- to the
16 TVT-O implant. That's the anterior view and posterior view of
17 the sacroiliac joint. The levator muscles, of course, are
18 identified here.

19 She also had diverticulitis. Diverticulitis is
20 generally asymptomatic. It can flare up. That's undisputed.
21 And the diverticulitis that she had, she had a flare-up around
22 the holidays in 2010, just a few months before she got the
23 TVT-O. And diverticulitis, just so you understand, that's
24 just pouches that form along the intestine and the colon, and
25 this episode that she had, it started in the upper left

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1 quadrant and it went down. And, yes, did it radiate down into
2 her pelvis?

3 But here's what's important about that in 2010. She
4 had an extensive workup two months before her TVT-O implant.
5 What does her own implanting doctor say when she's dealing
6 with the diverticulitis in the holiday season in 2010?

7 "Unlikely gynecologic origin." It was eventually attributed
8 to diverticulitis. Her implanting physician says that no less
9 than three times in her records. "Potentially
10 diverticulitis."

11 Let's talk about those medical issues. I said they
12 were well controlled and far apart. Did she have issues?
13 Prior medical history? We're not disputing that. This is the
14 SI complaint, diverticulosis -- -litis complaint, and the
15 levator spasm that we talked about. The levator spasm is
16 diagnosed after her TVT-O surgery. So when you consider the
17 evidence in this case, please do not forget proximity and
18 timing.

19 Dr. Siddique says that she was limited by what
20 happened to her. He believed that at the time it happened to
21 her and he believed it at the time his deposition was taken.
22 You're going to learn more about the warnings in this case
23 that were given by Dr. Byrkit. You're going to learn why they
24 were inadequate. I've shown you some of the reasons why they
25 were inadequate.

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1 She was not informed about the possibility of
2 permanent pain. That's from her deposition. She does not
3 know if she told Mrs. Huskey she could have completely new
4 pain. The consent form, the informed consent that I talked to
5 you about, was not specific to the TVT-O.

6 And you'll actually have this information in front of
7 you have as you review the evidence in this case and have an
8 opportunity to take it back to the jury room. I apologize,
9 but that's a bad copy. There were no TVT-O specific warnings,
10 and the warnings were just common to all surgery.

11 What did Dr. Siddique finally tell her when he --
12 after the surgery, after the injections, says to her, risk of
13 permanent pain. That's what she's living with.

14 What Ethicon knew. Thousands of chronic back pain --
15 I'm sorry, back -- thousands of chronic pain complaints. What
16 did they represent? Transient leg pain. Insertion and
17 removal methods fraught with risk. And you're going to hear
18 from medical witnesses that will talk about that, who actually
19 trained with the inventor of the TVT-O.

20 What did they represent? That the procedure was
21 shorter and easier. What Ethicon knew: Bad for active
22 patients. What Ethicon represented: No patient restrictions.

23 Safer alternatives were available. So when you're
24 considering whether this device was really necessary for Jo
25 Huskey, consider whether that information should have been

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1 provided in light of these alternatives.

2 Too much mesh. They represented TVT-O mesh is
3 lightweight.

4 The mesh is made of polypropylene, subject to
5 degradation. They said that the mesh is non-reactive and does
6 not degrade.

7 Called it the gold standard.

8 I just want to take the opportunity, I know I took a
9 lot of your time, and we will respect your time in this case
10 and try to move it along as quickly as we can. But these are
11 important issues and I hope that some of this has provided
12 context for some of the evidence that we're going to go
13 through in this case.

14 And I, on behalf of Jo and Allen and my entire team,
15 I appreciate it. So thank you.

16 THE COURT: Ladies and gentlemen of the jury, it's
17 10:25, but it would be more sensible to take our break right
18 now than to start the defendants' opening statement and then
19 stop after only five minutes.

20 When you retire to the jury room, at all times during
21 the case, do not discuss the case among yourselves or permit
22 anyone to discuss it with you or in your presence, don't watch
23 anything about it, listen to anything about it, see anything
24 about it, don't use any social media, computers, cell phone,
25 Twitter, tweet or make any electronic noise.

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1 I hope you enjoy your doughnuts and coffee. I'll
2 call you back in 15 minutes. Court stands in recess.

3 THE COURT OFFICER: All rise. Court is now in
4 recess.

5 (The jury left the courtroom at 10:27 a.m.)

6 (A recess was taken at 10:27 a.m.)

7 (The jury entered the courtroom at 10:43 a.m.)

8 THE COURT: Ms. Jones.

9 MS. JONES: Thank you, Your Honor. May I proceed?

10 May it please the court, counsel, ladies and
11 gentlemen of the jury.

12 Good morning. My name is Christy Jones, and along
13 with David Thomas over there, I have the privilege of
14 representing the doctors and scientists and men and women of
15 Johnson & Johnson and Ethicon.

16 Ethicon is a company that's owned by Johnson &
17 Johnson and, as you already know, Ethicon makes medical
18 devices, and one of the medical devices that Ethicon makes is
19 a device called TTVT-O, which is actually called tension free
20 vaginal tape, that's what the TTVT stands for. And as you know
21 now, Ms. Huskey's doctor, Dr. Byrkit, chose to implant the
22 TTVT-O in Mrs. Huskey in order to treat her stress urinary
23 incontinence.

24 It cured her stress urinary incontinence. It worked.
25 But Ms. Huskey, and we're here today because Ms. Huskey claims

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1 that she had certain injuries as a result of the use of that.
2 And there's three things that I want to talk to you about
3 today and three things that are important.

4 First, the TTV-O was an appropriate treatment for
5 Mrs. Huskey. She had stress urinary incontinence. It cured
6 her stress urinary incontinence.

7 Two. Ethicon's responsibility is to warn doctors,
8 that's important, doctors of the risks. And Ethicon did warn
9 doctors of the risk associated with the TTV, and in fact Dr.
10 Byrkit shared that information with Ms. Huskey.

11 And third, Ms. Huskey had health problems, including
12 some of the very ones she claims today, long before she ever
13 had the TTV.

14 Now, these are the three problems or the three points
15 that I really wanted to talk with you about this morning. But
16 frankly, after listening to Mr. Wallace, plaintiff's counsel,
17 there's something I want to address with you first because I
18 think I need to respond to it.

19 Mr. Wallace suggested that a manufacturer has a duty
20 to put patient's safety first, and a manufacturer has a duty
21 to insure that its products are safe, and that a manufacturer
22 has a duty to warn of the risk associated with the product.
23 And that's right. Of course that's true. And Ethicon did and
24 fulfilled all of those responsibilities.

25 Ethicon, in fact, developed a revolutionary and

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1 innovative product for the treatment of stress urinary
2 incontinence in women, a condition that has plagued women for
3 years. So revolutionary that it was immediately adopted by
4 doctors all over the world as the preferred method of
5 treatment of stress urinary incontinence in women. And
6 Ethicon continued to seek to study and to seek ways to improve
7 its devices over the years, exactly as you would hope a device
8 manufacturer would do.

9 And that's why, ladies and gentlemen, point number
10 one, the TVT-O was an appropriate treatment for Mrs. Huskey.
11 If we start at the, again, let me start a little bit with the
12 background on it, just bear with me. Stress urinary
13 incontinence is a condition that has haunted women for years.
14 It's a condition that will affect as many as one out of three
15 women at some point in our lives. You have accidental
16 unintentional loss of urine and it can be embarrassing, it can
17 be disruptive, it can affect women and how they live their
18 lives. And as a result of that, women have sought treatment
19 for this condition, and doctors have explored different ways
20 to treat this condition for decades.

21 It's so serious for women that women have been
22 willing to under go major abdominal surgery looking for a
23 cure. And that's the reason that the TVT was such an
24 important development.

25 Let me see if I can put this into perspective and

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1 explain a little bit, and I apologize that you're having to
2 look at the pelvic anatomy one more time. This is just
3 looking from the side view. You have the bladder, behind it
4 the vagina, in the back the rectum, and then you have the
5 urethra.

6 What's important is that before the TVT was
7 developed, the way doctors treated surgically stress urinary
8 incontinence was through major abdominal surgery where the
9 vagina was essentially pulled up to support the bladder and
10 the urethra to prevent the accidental loss of urine.

11 So if we look at this specifically, just to give you
12 an example, and I'm not a doctor so bear with me in my
13 descriptions here, what happened is is that the doctors would
14 go in and they would have roughly a four-inch incision in the
15 stomach to go in, and then they would turn around behind the
16 retropubic bone to the vagina, and they would then suture or
17 tack the vagina tissue up to the ligaments on the pubic bone.
18 This is the pubic bone here. This just looks at it if you're
19 looking down where they pull back the tissue, that's kind of
20 the way it looks.

21 If you look at another view of it, what you have here
22 is the bladder and the urethra, and you pull the vagina up to
23 hold the urethra in place. You stopped it by holding the
24 urethra in place, you supported those muscles and you would
25 prevent the accidental loss of urine.

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1 This procedure, and I roughly described it, sometimes
2 called the Burch procedure, you'll hear about that.
3 Plaintiff's counsel also mentioned what's called autologous
4 fascial sling procedure, and that procedure is a very similar
5 procedure where a sling is fastened or taken, made out of a
6 person's own tissue, to hold up the urethra. So what they do
7 is they cut a strip, either out of the leg or out of the
8 abdominal muscle, and they make a sling, if you will, out of
9 it. And then they do the same thing, they'll have this
10 four-inch incision, they'll tunnel down it to reach the
11 urethra, and in this case they also have to go up through the
12 vagina, a separate area to place the sling under the urethra
13 to kind of hold it, to hold it up.

14 Now, these are major surgeries that obviously involve
15 putting someone generally under general anesthesia or under
16 anesthesia and cutting them open. You have the risk of
17 serious complications like infections or bleeding or all the
18 complications that generally accompany any type of major
19 surgery. Long recuperative period, about four to six weeks.

20 In contrast to that, in contrast to that, and the
21 reason that what we're talking about today, the TVT-O, is that
22 the TVT-O is an alternative to major abdominal surgery. Let's
23 see if I can give you a little bit of background with it.

24 In the mid 1990s, the first midurethral sling, and
25 the midurethral sling is placed under the middle of the

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1 urethra there, was developed. It was developed in Sweden by a
2 doctor known as Dr. Ulmsten. You'll probably hear about Dr.
3 Ulmsten. Ethicon worked with Dr. Ulmsten to develop the
4 original TTV, the original tension free vaginal tape. That
5 device was very important. It was significantly different
6 from the major abdominal surgery because they were able to
7 take large needles and go up through the vagina and place a
8 sling made of mesh up under the urethra to hold it up.

9 So when we look at this, this is the original TTV,
10 and you just see what happens is they go up through the vagina
11 and then they place this sling around the urethra just so it's
12 supported. And then, rather than having a major abdominal
13 incision, stomach incision of the four inches, you have these
14 two little exit holes, almost puncture wounds, of which the
15 tape comes out.

16 Now, this was a significant development because the
17 procedure could be done in only about half an hour, it could
18 be done with a woman in and out of the surgical suite, she
19 didn't have to stay in the hospital all overnight in most
20 cases, and in most cases she could resume her activities in a
21 matter of days. So it was a significant advance.

22 It was first marketed in the United States in 1998
23 and immediately thereafter, immediately thereafter this became
24 the doctor's preferred method of choice to treat stress
25 urinary incontinence.

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1 Shortly thereafter, Ethicon, I'm not even sure I said
2 Ethicon, but Ethicon obviously is responsible for making the
3 original transvaginal tape and put it on the market in 1998.

4 After it had been on the market and became so widely
5 accepted, one of Ethicon's competitors began to develop and
6 market a different type of transvaginal tape, one that went
7 through the obturator foramen as you heard about this morning.
8 These are just the little holes of the obturator and so forth.
9 It was thought that this would be an advantage over the
10 original TVT because the tape could come out, would run to the
11 side, here, and out, rather than going up and risking the
12 potential puncture and placement of it up the bladder. So it
13 was thought that this was an improvement of the device.

14 About that same time as doctors got interested in it,
15 Ethicon began to work with a doctor named Dr. de Leval who is
16 at Liege University in Belgium. And Dr. de Leval was working
17 on developing and had clinical studies in women and was
18 developing what became the TVT obturator. The TVT obturator
19 was implanted basically the same way that the TVT, the
20 original TVT was, except for the way that the tape comes out
21 and actually comes out now in the legs. Dr. de Leval had
22 studies under way, Ethicon worked with him, and Ethicon then
23 began marketing the TVT-O in 2004 here in the United States.

24 Now, you may ask yourself a little bit about why I'm
25 talking about the TVT as opposed to the TVT-O which Ms. Huskey

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1 had, and I want to answer that question because I think it's
2 important that you understand that when you see both of them,
3 you understand that the TVT-O was, in fact, the logical
4 extension, if you will, off the TVT retropubic. The
5 retropubic is called the retropubic, again, because the tape
6 comes up behind the pubic bone and here it goes, it's called
7 the obturator because of course it goes through the obturator.

8 But what's important is that exactly the same tape
9 was used in both operations. The TVT and the TVT-O are made
10 of exactly the same material, exactly the same size material,
11 exactly the same amount of material is essentially left in the
12 body after it's placed there.

13 Now, I want to talk with you a little bit about the
14 mesh. The mesh that makes up the TVT-O, that's used there, is
15 what's called Prolene polypropylene mesh. It's important
16 because it's made of Prolene polypropylene. And I say Prolene
17 polypropylene for one very important purpose. Mr. Wallace
18 talked with you this morning about degradation of
19 polypropylene. Well, Prolene polypropylene is a very specific
20 kind and that will be important to us.

21 The Prolene polypropylene was first made by Ethicon
22 in sutures back in the 1950s. Those sutures that were made to
23 be used in any kind of surgery, whether it's heart surgery,
24 knee surgery, whatever, it would last a lifetime. That
25 Prolene polypropylene is exactly the same composition as what

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1 is used in the TVT mesh.

2 In the 1970s those same sutures were woven into a
3 mesh. It's just like you took the sutures and you wove them
4 up and you have a mesh, exactly the same thing. And that mesh
5 began to be used by doctors for treatment of primarily hernia
6 surgeries. It was used in the abdomen to treat hernias and
7 then doctors, some began to use them in other areas and in
8 pelvic areas. That was in the Seventies.

9 So long before this tape was ever used in the TVT in
10 1998, it had been used, the same mesh, identical, had been
11 used in thousands, if not hundreds of thousands, of men and
12 women for treatment of different conditions in the body.

13 In 1998 it was first used in the TVT, after Dr.
14 Ulmsten had done studies of it, beforehand, the use in women,
15 and finally in 2003 it was incorporated into the TVT-O.

16 So what we see is that long before it was ever used
17 in the TVT, it had been used, it had been studied in
18 laboratory studies, it had been studied in clinical studies,
19 and throughout that material had been shown to be safe and
20 effective, no suggestion at that point there was any kind of
21 degradation of the material at all.

22 One of the things that you will learn, that there
23 will be no real dispute about, is that the TVT and the TVT-O
24 are two of the most widely studied devices ever used in women.
25 In fact, there are over 2,000 studies in the medical

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1 literature that have looked at midurethral slings. And these
2 studies look at the issue of whether they're safe and whether
3 they work and they're effective, and these studies compare
4 them to the other like major abdominal surgeries to see if
5 they work effectively.

6 There are over a thousand studies or publications in
7 the medical literature dealing with the TVT and TVT-O.
8 Specifically, there are over a hundred randomized controlled
9 trials dealing with the original TVT, and over 60 dealing with
10 the TVT-O.

11 Now, I want to emphasize something because these were
12 important. These randomized controlled studies are studies in
13 which the device is implanted in women, and there's generally
14 two populations of women, some have the device and some don't,
15 and doctors follow those women and study them to see what
16 happens to them. They look at it to see whether the device
17 works, and they look at it to see whether there is some type
18 of complication. We have more complications in one side than
19 you do in the other. And so these types of studies are
20 considered to be the very best type of study that can be done
21 on medical devices.

22 We not only had all of these studies on the TVT and
23 the TVT-O, we have other studies that were done before they
24 ever went to market. For example, Dr. Ulmsten had studies
25 beginning in 1996. Dr. de Leval had studies in, again, in

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1 2003. And what we know is obviously there are hundreds of
2 other studies that I haven't put up here that I've referenced
3 earlier. And all of these, or at least the vast majority of
4 these, were done and performed before Mrs. Huskey got her
5 TVT-O in 2011. And consistently what these studies have
6 shown, consistently, is that both the TVT and the TVT-O are
7 safe and as effective as any of the major abdominal surgeries.

8 In fact, they've had studies that have gone and
9 looked at them, in the case of the TVT, for as long as 17
10 years. In the case of the TVT-O, it hasn't been around quite
11 as long, but there's studies going for as long as, you know,
12 five years. And if we look at these types of studies, they
13 looked at success rates. So these long term studies have
14 looked to see is it successful, does it work. And they
15 measure it two different ways. One is by objective standards.
16 And by objective standards means what the doctor can measure.
17 So can the doctor measure that, in fact, the woman is
18 continent, does not leak, when she is asked to perform certain
19 functions in the doctor's office.

20 And what these studies have shown, these are the long
21 term studies on the TVT, have shown that after as long as 17
22 years, ten years, 11 years, you have objective cure rates,
23 success rates, of anyplace between 84 and 91 percent. So
24 eight out of ten women after ten years are still perfectly dry
25 and it works.

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1 The studies have also looked at it another way, and
2 the other way they've looked at it is subjectively. And when
3 we say subjectively, what that means is how does the woman
4 feel about it. So the studies ask the woman, how do you feel
5 about the success of this procedure, how do you feel about
6 whether or not you think it works, and would you recommend it
7 to a friend. And what in the case of the TVT studies they've
8 shown is, again, you see very high subjective success rates,
9 the lowest one here being about 78 percent, going as high as
10 95 percent. The women considered it to be a success years and
11 years after they had the study.

12 We also have the long term studies on the TVT-O.
13 Again, as I said, they're a little bit shorter than the long
14 term because the TVT-O hasn't been around as long, but you see
15 there that you also have very high success rates with the
16 TVT-O, the lowest one here being a 73 percent success rate,
17 meaning that three out of four people thought it was
18 successful after five years. And on the long term studies,
19 what the women thought about it, you also had an 80 to 90
20 percent success rate, with the exception of one which was a
21 little bit of an outlier down to 62 percent.

22 But the important thing is that all of these studies
23 demonstrate that both women were satisfied with the TVT-O and
24 the TVT, and doctors thought that they had cured it.

25 Consistently all of these studies have shown that the

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1 devices are safe and effective long term when compared with
2 either the major abdominal surgeries or others.

3 That being the case, with all of these studies,
4 doctors immediately, as I said, I think I'm repeating myself
5 and I apologize, immediately began to use these devices to
6 treat women for stress urinary incontinence. They used them
7 because they found them to be safe and they used them because
8 they found them to be effective. And when plaintiff's counsel
9 suggested that they didn't look at safety, I suggest to you
10 that every one of these studies, every one of them, looked at
11 potential complications.

12 It's been so widely, so widely accepted that every
13 major organization of doctors who treat this condition, every
14 one of them, has endorsed the use of the midurethral sling.
15 They said it's a big advantage over what we had before. You
16 have efficacy, that means it works after five to ten years.
17 You have low complication rates. And these slings, the
18 midurethral slings, including the TVT-O, were now considered
19 the worldwide gold standard for treatment of stress urinary
20 incontinence by doctors.

21 And all of these statements, ladies and gentlemen,
22 were issued after Ms. Byrkit had her surgery. They remain
23 true today. Indeed, some of these studies, some of these
24 statements, were made as late as 2014.

25 But notwithstanding the fact that doctors worldwide

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1 use the TVT and TVT-O to treat stress urinary incontinence,
2 every surgery has complications. And surgery involving the
3 pelvic region, or to treat stress urinary incontinence,
4 regardless of what it is, has the potential for complications.

5 The old surgical abdominal approach had these
6 complications, and there's also a potential for the
7 complication with the TVT and the TVT-O. They include such
8 things as pain during intercourse, pain, bleeding, infection.
9 They're all possible risks. But what's important about this,
10 and the reason I'm showing this to you, is that doctors
11 performing these surgeries and the major abdominal surgeries
12 at the time all knew about these risks because they
13 accompanied the abdominal surgeries long before we got to the
14 TVT-O and the TVT. So everybody recognized that this was a
15 possible risk. And what the studies show today is that these
16 complications are very rare, generally in the context of the
17 TVT or the TVT-O, but nonetheless they are potential
18 complications.

19 Pain is a complication with every procedure. Clearly
20 one of the things that is warned on and we'll see is the
21 potential risk of pain. And to be candid, there are studies
22 and you will probably hear that there are some suggestion of
23 an increased risk of pain, particularly leg pain or thigh pain
24 with the TVT-O because that's where the tape exits, if you
25 will, over other things. But, generally, that pain resolves

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1 in a matter of hours or days, and certainly within a few
2 weeks.

3 What's important for us today in this case is that
4 Ms. Huskey doesn't have that, never complained about it.

5 There are also some very specific risks that are
6 associated with any foreign body that you put in a body.
7 Anytime, whether it's a knee replacement or a heart
8 replacement or whatever, there's always the possibility of
9 something happening as a result of having that foreign body
10 implanted. What happens is when that device is implanted, the
11 body, just as part of its normal healing process, has what's
12 called kind of a foreign body response. And what that is a
13 inflammatory type response. In the case of the TVT-O, that
14 inflammatory response is something that's anticipated because
15 what happens is the inflammatory response helps the tissue
16 actually grow into the holes in the mesh, the pores of the
17 mesh, and that helps hold the tape where it's supposed to be.
18 It's a little bit like, not very scientific, but it's a little
19 bit like Velcro, it holds it there. And there's always the
20 possibility that you can, that that can potentiate an
21 infection or the inflammation can cause that, but that is
22 extraordinarily rare, very rarely happens.

23 What does sometimes happen is that you have what's
24 called mesh exposure, which is what we're dealing here with
25 Ms. Huskey, where the tissue around the mesh will -- where the

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1 mesh will become exposed in the tissue. So, for example, if
2 it's exposed in the tissue of the vagina, it may pose some
3 problems during intercourse or may be somewhat tender.
4 Usually that exposure can be treated either -- sometimes it
5 doesn't occur, doesn't have any pain or anything else
6 associated with it -- a lot of times it can be treated just
7 with an estrogen cream, and sometimes by surgeons just going
8 in and clipping it away. But clearly mesh exposure is a risk
9 that was known and explained as it related to the TVT-O. That
10 occurs in, depending on the study, somewhere in the
11 neighborhood of two to three percent of patients.

12 Regardless, regardless, what is clear is that even
13 with the complications, what the studies have shown is that
14 when you had a TVT-O as opposed to a major abdominal surgery,
15 it's done with less anesthesia, shorter operating time,
16 shorter hospitalization time, you're able to resume activities
17 quicker, with generally a low rate of complications, but lasts
18 just as long. For those reasons, for those reasons, the TVT-O
19 was an appropriate treatment for Mrs. Huskey.

20 So I want to turn now to point number two that I
21 mentioned, and that is that Ethicon's responsibility is to
22 warn the doctors of the risks. As I mentioned, every surgery
23 has complications, and those complications are what surgeons
24 or doctors need to know about, and that's what the
25 manufacturer's duty is to do is to warn the doctors.

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1 Ethicon tried three different ways or several
2 different ways to make sure that doctors were aware of the
3 risks. First, it provided professional education to doctors.
4 In providing professional education to the doctors, what I
5 mean is they would give seminars where they would come and
6 listen to a lecture, but they would also provide them the
7 opportunity to be trained on how to insert the TTVT-O on
8 cadavers, or to observe surgery by more experienced surgeons,
9 or to have a more experienced surgeon watch them so they could
10 insure that they knew how to insert the TTVT-O correctly.

11 We also provide instructions for use with every
12 TTVT-O, and those instructions for use include the risks -- not
13 only how to do it, how to do the procedure, but include the
14 risks associated with it. And then the third, the patient
15 brochure was provided to doctors to help them counsel their
16 patients on risks.

17 If we look specifically at the risks that are
18 included in the IFU, what's important is this is information
19 that's given to doctors. You may puncture vessels or nerves.
20 You may end up having to have a repeat surgery if there's a
21 problem here. You may have, the erosion or extrusion relates
22 to the mesh exposure. You can have inflammation. You may
23 have an infection. And all of this information was given to
24 doctors. And Dr. Byrkit, Mrs. Huskey's surgeon, has testified
25 -- and you will see her deposition exactly as it is -- that

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1 she was aware of these risks, that she had used the TVT-O
2 repeatedly, and indeed that she counseled Ms. Huskey on the
3 risk.

4 In fact, she was asked, "Would the possibility or the
5 risk of pain after the procedure be present in all of the
6 surgeries?" "I would expect that there could be pain in any
7 of the procedures, yes."

8 She's asked specifically about what she discussed
9 with Mrs. Huskey and what she knew, and she said that she
10 specifically discussed with her that mesh can erode and there
11 could be complications, potentially complications after mesh
12 erosion that need to be treated.

13 Then we asked about pain with intercourse, and she
14 talked about the fact that although she couldn't say
15 specifically that she used the words "pain with sex" or "pain
16 with intercourse" in talking with Ms. Huskey, that she
17 certainly knew it and thought that it was obvious because you
18 were operating in the vagina and the pelvic area.

19 The records in this case show that Ms. Byrkit --
20 Dr. Byrkit counseled Ms. Huskey three different times about
21 the risks associated with the TVT-O, and specifically talks
22 about the risk of infection, the risk of damage to internal
23 organs, the risk of mesh erosion, the risk of the need for
24 further surgery to remove the TVT. So clearly Dr. Byrkit
25 recognized the risks that were associated there and, according

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1 to the records, discussed them with Ms. Huskey.

2 Now, although Ms. Huskey has testified that she
3 doesn't remember exactly these discussions, the medical
4 records also indicate that she was given a pamphlet on TVT,
5 the patient brochure, the first time she consulted Dr. Byrkit
6 about that. Again, we don't, Ms. Huskey doesn't have that
7 pamphlet any more, we don't have the one specifically that was
8 there, but the one that was in effect beginning as early as
9 2008, almost three years before Ms. Huskey's surgery,
10 specifically warned of pain, pain with intercourse, the mesh
11 material becoming exposed, and exposure may require treatment.

12 This is important, ladies and gentlemen, because what
13 the evidence will show is very specifically that Ethicon
14 warned the doctor of the risks associated with the TVT-O, and
15 in this case Dr. Byrkit's testimony is that she shared those
16 risks with Ms. Huskey.

17 Third. We talked about Ms. Huskey had health
18 problems before she had the TVT-O. If we look and begin with
19 Ms. Huskey's medical records in 2010, in early 2010, here in
20 March, she went to see the doctor with increased urinary
21 symptoms indicating that she was having some stress
22 incontinence. This is the first time, I think, that she
23 complained of stress urinary incontinence in the medical
24 records, certainly in 2010. And noted at that time that she
25 works in physical therapy, actually teaches women's pelvic

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1 strengthening. I mention that only because while we're
2 talking about the surgical options here for treatment of
3 stress urinary incontinence, there are sometimes doctors
4 initially try and get women to do exercises to try and
5 strengthen their pelvic muscles to see if they can avoid
6 surgery that way, and that's what Ms. Huskey as I understand
7 was looking at. And she thought that this was, it was, the
8 doctor thought that, it was alarming to her.

9 In 2010, a year before Ms. Huskey got the TVT-O, was
10 a little bit of a difficult year for her. You can see she had
11 the urinary problems. She lost her job. She was treated for
12 stress and depression. And then in the fall of 2010 she began
13 to complain and see doctors for abdominal pain, suprapubic
14 pain, pelvic and left lower quadrant pain, back pain,
15 vaginitis and so forth. And this all starts in about October
16 of 2010. It culminated when she was hospitalized following a
17 trip to the emergency room in December of 2010.

18 And when she went to the emergency room in December
19 of 2010, she was complaining about chronic left lower quadrant
20 pain that had existed for the last month and a half, that had
21 been rated seven to ten for four days, was radiating into her
22 back, and it became significantly worse that day. She goes to
23 the emergency room and she undergoes a series of tests over
24 the next two or three days. She's actually hospitalized and
25 doctors do a number of tests to look at that, including

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1 looking and exploring abdominal or gastrointestinal
2 explanations. And she was ultimately diagnosed with
3 diverticulosis where you have some pockets in the rectum.
4 They also looked at whether or not this was being caused by
5 musculoskeletal problems, spasms or whatever in terms of her
6 pelvic pain.

7 Let me just say that the records will show, you will
8 see, that no definitive cause for her pain was ever identified
9 at this point in time. It was at this point in time and
10 during this hospitalization that she actually saw Dr. Byrkit
11 for the first time. And it was after that when she first saw
12 her in the office on January 27, 2011.

13 When she sees her January 11 -- January 27, 2011, she
14 goes in to, kind of in part as a follow-up to her
15 hospitalization, and it says she has multiple complaints today
16 including left lower quadrant pressure mainly after
17 intercourse, a constant vaginal irritation. And then we talk
18 about she's leaking with urine and she describes the symptoms
19 of the stress urinary incontinence.

20 This is why she went to see Dr. Byrkit. It was at
21 this visit when she was talking to Dr. Byrkit that they
22 discussed the potential treatment of her stress urinary
23 incontinence and the potential treatment with the TVT. And
24 it's referenced there, she gave her a pamphlet and they
25 discussed it. And as I mentioned, she, according to the

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1 records, talked with Ms. Huskey about it on three different
2 occasions.

3 Following that, on February 23, Ms. Huskey actually
4 had the surgery with the TVT-O implanted. Now, during the
5 course of the surgery Dr. Byrkit had a little bit of a
6 difficult time because she was inserting the TVT-O up through
7 the vagina and she actually did what's called buttonholing,
8 which meant that the mesh was actually kind of coming through
9 the vagina, the vaginal tissue rather than being behind it.
10 It's just a surgical risk that doctors know about when they're
11 doing that, and what she did was she removed the tape, sewed
12 up the little holes, repassed the tape, and placed the rest of
13 the TVT-O then without any further complications.

14 Ms. Huskey went home, cured, no problems with stress
15 urinary incontinence, had no problems for a week or so. And
16 then, about March 5 or so, she was vacuuming and I think
17 playing with the dog or something, I think, and noted she had
18 some vaginal bleeding. She called the doctor. Ultimately it
19 wasn't bad enough for her to go back in, but she did go back
20 in to see Dr. Byrkit on March 9. This is her first post op
21 visit, a little over two weeks afterward.

22 At the time that she went in to see Dr. Byrkit then,
23 she was dry, having no problems with stress urinary
24 incontinence. She was having -- she reported that she was
25 pleased with her surgery. She was having no problems, no

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1 further problems with bleeding. And on the examination Dr.
2 Byrkit found that she was not tender, had no complaints of
3 pain at all.

4 Now, she did note, Dr. Byrkit did note at that time
5 that there was a small exposure of the mesh in the vagina.
6 She discussed it with Ms. Huskey, suggested that she use the
7 Premarin cream, which is the estrogen cream, just to see if
8 that would take care of it, but it was causing Ms. Huskey no
9 problems, she had no pain or tenderness around it. There was
10 no indication that she had any type of infection.

11 And on March the 16th, a week later, Ms. Huskey
12 actually goes back to work at a new job as an assistant
13 physical therapist where she's providing therapy and working
14 with patients in a pool and so forth, so she's gone back to
15 work by March the 16th without having any problems whatsoever.

16 She comes back in on April the 6th for another post
17 op visit, and again, at this time she's not having any
18 problem. She's not leaking, she's gone back to work, she's
19 not tender, she's not having any signs of infection, but Dr.
20 Byrkit again notes that the mesh is still exposed. She talks
21 with Ms. Huskey about it, according to her records and her
22 testimony, and they talk about various treatment options about
23 whether you could do nothing, use the cream, whether they
24 ought to go back in and try and cover over it, and they decide
25 to do nothing, but in fact she suggests to her to wait until

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1 after she has intercourse so she can see whether it's causing
2 any problems.

3 And in fact, then she comes back for her annual exam
4 on May 20, and when she comes back for her annual exam on May
5 20, Ms. Huskey reports that she's walking, biking, in the pool
6 one to two hours a day, five days a week. Again, she's not
7 leaking, but she does report that she has had some discomfort
8 with intercourse. And Dr. Byrkit notes that she still has a
9 small mesh exposure. Again, no indication of tenderness with
10 the mesh exposure and no discharge or indication of anything
11 like infection.

12 Nonetheless, they decide to have another surgery in
13 order to cover up the mesh, if you will, sew over the mesh,
14 and so Dr. Byrkit goes back in and takes the plaintiff back to
15 surgery to do that on June 29.

16 Two weeks later, July 15, Ms. Huskey goes back in to
17 see Dr. Byrkit. At that point, even though the surgery went
18 well and without complications, at that point she complains of
19 lower abdominal pain for two days. That's the first complaint
20 of pain following the TVT-O surgery in Mrs. Huskey's records.

21 As counsel noted earlier, she was still seeing a
22 small one centimeter exposure and reported that to Ms. Huskey.
23 Ms. Huskey was upset and she referred her, Dr. Byrkit then
24 referred her to Dr. Siddique, who she saw on August 29 the
25 first time. And when she sees Dr. Siddique on August 29,

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1 she's complaining of pelvic pain, rectal and pelvic pain due
2 to diverticulosis.

3 Dr. Siddique examines her, notes that she still has
4 some exposed mesh, and they make plans for a surgery to remove
5 or to excise the mesh, but it's delayed until about November.
6 He scheduled it about three months away as opposed to
7 immediately.

8 And in the interim he actually does an cystoscopy on
9 October 12, and what's important about that is that that was a
10 procedure that they went in to see whether or not she was
11 having any mesh anywhere else, whether there had been any
12 erosion into the urethra or into the bladder or anything, and
13 they didn't find anything, no problems.

14 So on November 18 Dr. Siddique excises the mesh, the
15 tape up underneath the urethra, without any problems according
16 to his records.

17 Now, this is important. Dr. Siddique removed the
18 mesh. When he removed the mesh, he sent it to pathology or
19 whatever the normal places are, but he noted nothing unusual
20 about the mesh. Dr. Siddique didn't note any degradation of
21 the mesh. He didn't note anything unusual about the
22 appearance of mesh. And we don't have the mesh, it just
23 doesn't exist any more, and so you will not have any evidence
24 before you, nor will anyone be able to talk to you based upon
25 an examination of the mesh that suggests that Ms. Huskey's

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1 mesh degraded or didn't perform in any way, shape or form in
2 her body.

3 After this, Dr. Siddique followed Ms. Huskey for
4 several months and, Ms. Huskey, in all candor, saw some other
5 doctors, and went to see some other doctors complaining of
6 pelvic pain and dyspareunia. And dyspareunia is just pain
7 with sex.

8 And those doctors consistently looked to see whether
9 or not there was any explanation for the cause of her
10 complaints of pain. And you're going to hear from some of
11 those doctors.

12 One of those doctors is Dr. Mueller. Dr. Mueller is
13 a urogynecologist, and a urogynecologist is a specialized
14 doctor who treats women with stress urinary incontinence and
15 other conditions and is the one that actually performs this
16 type of surgery. But she went to see, was referred to see Dr.
17 Mueller for pain, and Dr. Mueller examined her. And Dr.
18 Mueller ordered what's called a pelvic ultrasound to look at,
19 and she ordered the ultrasound so she could look at it and see
20 whether there was anything in Mrs. Huskey's pelvis that would
21 suggest any reason for the pain.

22 The reason she did the ultrasound, Were you able to
23 determine through your examination or through the ultrasound
24 what that area was, had been referred to. And she said no,
25 but I was able to determine it wasn't mesh.

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1 And then she was asked whether or not there were any
2 other abnormalities shown on the ultrasound, and she said no.
3 It was perfectly normal.

4 Ms. Huskey also consulted Dr. Ogunleye. Dr. Ogunleye
5 is another urogynecologist and he also examined her. And this
6 is what he said: Where she had the pain is not where a TTVT-O
7 would be. I didn't see anything on her, and she is having the
8 pain more on the posterior side of the vagina, that means
9 frankly away from where you would have expected the TTVT-O to
10 have been, and not where someone who had a TTVT-O would have
11 mesh placed to cause the pain.

12 That's what Mrs. Huskey's doctors have said.

13 So I suggest to you, ladies and gentlemen, that in
14 the course of this case it's going to be important to listen
15 to the evidence to determine when Ms. Huskey began to
16 experience the very claims -- the very pain and injuries that
17 she claims to have sustained, and two, whether or not they
18 have anything to do with the TTVT-O.

19 Now, when we were here last week Dr. Goodwin -- Judge
20 Goodwin instructed you and told you that the plaintiff, told
21 you a little bit about the plaintiff's case and what the
22 claims were and that the plaintiff had the burden of proof in
23 this case. The plaintiff has essentially two main claims that
24 Judge Goodwin talked with you about, one of which is a failure
25 to warn claim, that the plaintiff has to prove that she failed

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1 to adequately -- the plaintiff has to prove that Ethicon
2 failed to adequately warn Dr. Byrkit of the risks associated
3 with the TVT, and, two, that that failure to warn caused the
4 injuries to Ms. Byrkit, I mean Ms. Huskey.

5 What you will also learn is that it's not necessary
6 to warn a doctor of things that they already know, or which
7 they say they already know and recognize. But we have already
8 talked about that and I don't want to go back over and talk
9 about the fact of the warnings. What I do want to talk to you
10 is the plaintiff's second claim of defective design.

11 Do you remember what Dr. -- what Judge Goodwin said
12 was that the plaintiff has a defective design claim, and in
13 order to prove that she must prove that the TVT-O, that there
14 was a condition in the TVT-O that made it unreasonably
15 dangerous, and that that condition proximately caused her
16 injuries.

17 Now, when we're talking about, when I was listening
18 to counsel this morning, how plaintiff intends to prove
19 defective design, it appears that there are three particular
20 issues. One is that they claim that the mesh that Ms. Huskey
21 had was a laser-cut mesh; and it was. Two, that the mesh
22 somehow degraded. And three, that maybe there was too much
23 mesh or the wrong size or type of mesh that was there. So let
24 me quickly address those.

25 First of all, when we're talking about laser-cut

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1 mesh, obviously this is blown-up and very difficult, but what
2 we're talking about here, we're talking about laser-cut mesh,
3 the mechanically-cut mesh that was in the original TVT and
4 TVT-O is just like if you took a paper cutter or pair of
5 scissors at the school and slashed it. That's what a
6 mechanically-cut mesh is. The laser-cut mesh is just if you
7 cut it with a laser, so it kind of melts the edges of it, if
8 you will. Other than that, other than the way they are cut,
9 these two pieces of mesh are identical. Identical. And the
10 only thing that may be a little bit different is that here on
11 the edges it may be a little bit stiffer.

12 Now, the reason that that laser-cut, that the change
13 to the laser-cut was made, was because some doctors complained
14 about the appearance of the mechanically cut mesh and they
15 thought that there was some fraying on this edge. So the move
16 to the laser-cut mesh was seen an improvement to the product
17 to address some of the concerns that had been expressed by
18 doctors.

19 What's important about the laser-cut mesh is this:
20 One, it's identical in every other respect to mechanical-cut
21 mesh that's been out there for years; two, Ethicon tested and
22 evaluated the laser-cut mesh to determine whether or not there
23 would be any change in the physical properties of the mesh
24 that you would be expected to have any clinical effects; and
25 three, that there would be no evidence whatsoever that the

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1 laser-cut mesh had any medical effect on Mrs. Huskey.

2 The second point plaintiff raises, the claim that the
3 polypropylene mesh somehow degrades. The reason I started
4 with the sutures, talking about the sutures, ladies and
5 gentlemen, is because the sutures are made of exactly the same
6 material. They've been used in the body for over 50 years
7 now. They're placed in the body with the expectation that
8 they're going to last a lifetime. And in fact, that's what
9 happens.

10 The mesh is made of Prolene polypropylene, that's a
11 special formulation with some antioxidant characteristics to
12 preclude it from degrading in certain circumstances. As I
13 said before, there will be no suggestion or indication that
14 the mesh itself that was removed from Ms. Huskey was in some
15 way degraded. There will be no evidence that degradation had
16 any clinical or medical effect on Ms. Huskey.

17 Third point that is sometimes raised or suggested is
18 that there's too much mesh, that this is a heavier weight
19 mesh, that the hernia mesh is a heavier weight mesh than used
20 in other applications. They claim that the pore size is too
21 small and there's a reference to it as large bore, small bore.
22 I want to just say these things about it: One, a large bore
23 mesh is defined as a mesh that has pores, little holes, larger
24 than 75 microns. The pore size of the TVT is over a thousand
25 microns. Granted, it's obviously blown up, that one inch

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1 here. This would be considered a large bore mesh, this is a
2 larger bore mesh. This is the pore size of the TVT-O.

3 Now, the only reason that I raise that with you is
4 that in some of the documents that you will see, and maybe
5 even some of the testimony that you will hear, there's going
6 to be reference to -- in fact, on the plaintiff's slide they
7 suggested that there's old construction hernia mesh. There's
8 a suggestion that the old construction hernia mesh and the
9 mesh that was used in the TVT-O is somehow a small bore mesh
10 that has problems with it. And I have to tell you, frankly,
11 ladies and gentlemen, that there's some sloppy language in the
12 documents where they refer to it as small bore mesh, probably
13 because subsequently a larger bore mesh used in other
14 applications for pelvic or repair surgery and hernia surgery
15 was developed. The right way to do it would have been to call
16 it large bore and extra large, or large and larger. But as
17 you can see how it happens, somebody referred to it as small.
18 It may be confusing to you when you look at some of the
19 documents. I'm going to ask you when we talk and look through
20 the documents and you hear the testimony of some of the
21 witnesses, it will be important to discern or listen to which
22 mesh they're actually talking about.

23 What is important is that it is a large bore mesh.
24 It was a large bore mesh when initially tested by Dr. Ulmsten
25 in the mid 1990s, it's still a large bore mesh, and study

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1 after study after study has shown it to be safe and effective.

2 Now, it's time for me to slow down. This will be the
3 last time I have an opportunity to address you until at the
4 end of the case. As Judge Goodwin has told you, the plaintiff
5 gets to present her evidence first, and I do ask you, as Judge
6 Goodwin cautioned you, to keep an open mind until you hear
7 from our witnesses, which will probably be several days from
8 now.

9 At the end of this case I think what you will find,
10 based upon all of the evidence, is that, in fact, the TVT-O
11 was an appropriate device to treat Ms. Huskey's stress urinary
12 incontinence, that Ethicon warned of all of the conditions
13 that Ms. Huskey claims to have experienced, and these were all
14 done by Dr. Byrkit, and that the product was not defective.

15 Stress urinary incontinence, ladies and gentlemen, is
16 a condition for which women need treatment and have been
17 seeking treatment for decades and decades. The proof will
18 show that the TVT and the TVT-O were remarkable devices needed
19 by women and doctors, and that they're safe and effective.

20 And so at the end of the case, I'll come back to you
21 and I'll ask you to return a verdict in favor of Johnson &
22 Johnson and Ethicon.

23 Thank you.

24 Thank you, Your Honor.

25 THE COURT: Ladies and gentlemen of the jury, I

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1 rarely vary from the schedule, but we would barely get the
2 witness sworn and it would be noon, so we'll be back at five
3 minutes till one. We'll take a break for lunch.

4 During the lunch hour do not discuss the case among
5 yourselves, permit anyone to discuss it with you, or in your
6 presence. Don't read anything about it, watch anything about
7 it, listen to anything about it, use any social device, social
8 media, computer. I think you'll get the drift after I say
9 this about 50 times. Actually I know you got it the first
10 time, but I've got to be sure somebody doesn't think I got it
11 wrong.

12 Have a good lunch. We'll see you back.

13 (The Jury left the courtroom at 11:55 a.m.)

14 THE COURT: Court's in recess.

15 (A recess was taken at 11:56 a.m.)

16 (The jury entered the courtroom at 12:55 p.m.)

17 COURT SERVICES OFFICER: All rise.

18 THE COURT: Good afternoon. I trust you had a
19 pleasant lunch. We're ready to begin the presentation of the
20 evidence.

21 The plaintiff, if you will call your first witness.
22 Mr. Wallace?

23 MR. WALLACE: Yes, Your Honor. Dr. -- the plaintiffs
24 would call Dr. Scott Guelcher to the stand, please.

25 THE DEPUTY CLERK: Sir, if you'll please raise your

—GUELCHER - DIRECT - WALLACE—

1 right hand.

2 (**SCOTT GUELCHER, Ph.D.**, HAVING BEEN DULY SWORN, TESTIFIED AS
3 FOLLOWS:)

4 THE WITNESS: I do.

5 THE DEPUTY CLERK: Thank you. Please take the
6 witness stand.

7 THE COURT: You may proceed.

8 MR. WALLACE: Thank you, Your Honor.

9 (DIRECT EXAMINATION OF SCOTT GUELCHER, PH.D., BY MR. WALLACE:)

10 Q. Could you please introduce yourself to the jury.

11 A. My name is Scott Guelcher. I'm currently an associate
12 professor of chemical engineering at Vanderbilt University in
13 Nashville.

14 Q. How many years of experience have you had in chemical
15 engineering?

16 A. Over 20 years. Yeah.

17 Q. And have you ever worked with medical device companies
18 before?

19 A. Yes, sir. My current research, I'm a professor of
20 chemical engineering, but my research is in the area of
21 biomedical materials and a number of these materials, we're
22 working with companies to determine the products for human
23 health such as bone void fillers, other types of bone grafts
24 and products for healing foot ulcers and these types of
25 products.

—GUELCHER - DIRECT - WALLACE—

1 Q. Dr. Guelcher, rather than marching through your C.V.,
2 what I'd like to do is I have prepared a PowerPoint that
3 outlines some of your qualifications and some of the topics
4 you'll talk about today. If we could show that on the screen,
5 please. Counsel?

6 MR. THOMAS: Do you mind if have a copy?

7 MR. WALLACE: We are getting a printer.

8 THE COURT: Do you have -- do you have any problem
9 with just going ahead?

10 MR. THOMAS: No, Your Honor.

11 THE COURT: I figured you looked at it before.

12 MR. THOMAS: I haven't seen the PowerPoints, but
13 that's fine. We'll go ahead.

14 THE COURT: All right. Go ahead.

15 MR. WALLACE: Thank you, Your Honor.

16 BY MR. WALLACE:

17 Q. You've already talked about working at Vanderbilt
18 University. Can you tell me about the textbook on
19 biomaterials that's listed there on that slide?

20 A. So, a number of years ago, I co-edited a textbook on
21 biomaterials, and this covered a number of different types of
22 biomaterials that are used for implants and we talked about
23 properties of the materials that are used in the clinic, and
24 this was intended primarily as a teaching textbook for
25 undergraduate and graduate students.

—GUELCHER - DIRECT - WALLACE—

1 Q. Okay. When you talk about biomaterials, what are you
2 referring to?

3 A. So, these are materials that their purpose is to be
4 implanted in the human body and to serve some goal, either
5 healing bones, say, or hernia mesh or these different types of
6 materials that have been designed to achieve a medical goal.

7 Q. It says that you've given over 200 scientific
8 presentations. We obviously don't want to hear about all of
9 them. But can you tell us what you mean when you refer to
10 scientific presentations?

11 A. So, these are presentations given in meetings or
12 scientists working in a certain area. For example, there is a
13 Society for Biomaterials, and we all meet once a year and
14 present our latest research, my students and I present at
15 these meetings, and there is a number of them that are listed
16 there that I attend regularly.

17 MR. WALLACE: Can we go to the next slide, please.

18 THE COURT: Do we have copies for defendants now?

19 MR. WALLACE: Yeah.

20 The one -- just a housekeeping issue.

21 Dr. Guelcher --

22 THE COURT: We have the jury monitors on. That's one
23 of the reasons I wanted to have the defendants look at it, to
24 be sure there's no objection before we go further.

25 MR. WALLACE: Sure, thank you, Your Honor.

—GUELCHER - DIRECT - WALLACE—

1 THE COURT: So let's just hold for a second.

2 MR. WALLACE: Sure.

3 MR. THOMAS: Do you want me to review what's on the
4 monitor, Your Honor?

5 THE COURT: No, I asked them to go get the rest of
6 them. I didn't realize there was going to be more than one.

7 MR. THOMAS: Thank you.

8 MR. WALLACE: We had a -- Your Honor, we just had a
9 slight IT problem over lunch.

10 THE COURT: Okay.

11 MR. WALLACE: There's, apparently, the first-day
12 jitters somehow infected the IT.

13 THE COURT: There is a what?

14 MR. WALLACE: We had some first-day jitters, I think,
15 in the room outside where we're printing some things, and we
16 weren't able to print. So I apologize, Your Honor.

17 THE COURT: Well, you're apologizing to the right guy
18 because I never have a problem with IT.

19 (Laughter.)

20 MR. WALLACE: I don't, either, Your Honor.

21 THE COURT: If you can't print it, we'll -- could you
22 take it over and show it to them?

23 MR. WALLACE: Sure. And I will represent to -- I
24 believe counsel has seen something like this previously, but
25 I'll represent to you that the first three pages and perhaps

—GUELCHER - DIRECT - WALLACE—

1 the first 15 or so minutes is strictly going through the
2 doctor's background, if that's okay with you.

3 MR. THOMAS: That's fine.

4 THE COURT: All right. Let's go ahead and proceed
5 with it.

6 MR. WALLACE: Thank you.

7 BY MR. WALLACE:

8 Q. So let's go back to that screen, Dr. Guelcher. I see a
9 lot of what I call acronyms, DOD, AFIRM, et cetera. Can you
10 just quickly walk through each of those and tell the jury what
11 they mean and a little bit about the grant process?

12 A. So, as a professor in the engineering school at
13 Vanderbilt, one of my responsibilities is to write grant
14 applications to federal agencies, to receive money to support
15 the research that I use to pay students that I pay for
16 materials. And these are a number of funding agencies. So
17 the first, the NIH, is the National Institutes of Health.

18 There is an institute that focuses on arthritis and
19 bone diseases. I have funding from them.

20 The NCI is the National Cancer Institute, and in
21 these types of programs, we're interested in the problem of
22 how does breast cancer damage bone, how does it metastasize in
23 bone, why does that happen, how do we treat it?

24 The last one is probably familiar to everyone. DOD
25 is the Department of Defense, and the Department of Defense

—GUELCHER — DIRECT — WALLACE —

1 has a very large program called Armed Forces Institute of
2 Regenerative Medicine, that's AFIRM, and that's a program that
3 involves about 20 universities and we're all working together
4 to find better treatments for soldiers that are injured in the
5 conflicts in Iraq and Afghanistan.

6 So, my primary contribution there is on bone grafts
7 to repair the mandible, so there's some very bad craniofacial
8 injuries. Survival rates are high in these wars, but soldiers
9 have devastating injuries that affect their quality of life.
10 So we're working to improve that through that program.

11 And the last one is the National Science Foundation,
12 which is -- has a very important education mission as well,
13 training grad students, so those are currently agencies that
14 I've applied for funding and have grants through them right
15 now.

16 Q. Do you have a particular area of research as it relates
17 to wound healing, Dr. Guelcher?

18 A. So, we are designing tissue grafts for healing skin, so
19 that would include things like diabetic foot ulcers. It would
20 also include problems with the wound vac, so you have a very
21 bad wound, they can put a vacuum on it to kind of clear it out
22 and help it heal better. We're working with a company to
23 design better foams for this procedure. So we work with a
24 number of wound-healing companies.

25 Q. Beyond the experience that you've described, you actually

—GUELCHER - DIRECT - WALLACE—

1 worked at chemical companies before. Is that right?

2 A. That's right.

3 Q. Can you tell us a little bit about that?

4 A. So, right after college, I worked for Eastman Chemical
5 Company in Upper East Tennessee. There I was working on
6 polyesters, nutritional supplements such as vitamin E, vitamin

7 A.

8 After my Ph.D., I worked here in South Charleston, at
9 the Tech Center for about three years, so I was there when
10 Bayer had a facility at the Tech Center, as well as Dowe. I
11 worked a lot with the South Charleston plant, just
12 trouble-shooting problems there, improving their processes,
13 and this was all polyurethane intermedia when I was at Bayer.

14 Q. Okay. Can you do me a favor? I just want to break that
15 up into two parts because you mentioned polyurethane. You
16 mentioned plant. You mentioned South Charleston. Could you
17 just take those one at a time for us?

18 A. Okay. So I started off at Bayer as a research engineer,
19 working in the polyurethanes division, and my responsibilities
20 there included designing new products that we would then
21 translate to the plant. So we would make some improvement in
22 the lab, and then we'd work with the plant to make sure that
23 they could do this in a cost-effective way. I did that for
24 about three years, until I left in 2003.

25 Q. From Charleston?

—GUELCHER — DIRECT — WALLACE —

1 A. From South Charleston, yeah.

2 Q. And when you left South Charleston, West Virginia, where
3 did you go?

4 A. Then I went back to Pittsburgh for a post-doctoral
5 fellowship in biomedical engineering. That's when I shifted
6 fields somewhat.

7 Q. In addition to working for chemical companies as an
8 employee in your research, have you ever consulted with
9 medical device companies or other chemical companies?

10 A. Yes. So, I've done a fair amount of consulting work with
11 biomedical device companies, we're working with a -- a major
12 goal in my research is what we would call "translational."
13 So, that is, we try to discover things in the laboratory that
14 are new and then translate that to help people by making
15 better products. That's a very difficult thing to do because
16 universities do research and companies make products.

17 So, a lot of these I've been working on for some time,
18 but we work with the company to translate what we do in our
19 laboratory to make a product better, and then the company will
20 license this and then turn this into a commercial product. So
21 I have several projects like that going on right now. So, a
22 very keen interest of mine is innovation in the biomedical
23 device industry, is a very important thing to me. So...

24 Q. Have you worked in the field of polymers, Dr. Guelcher?

25 A. So, I've been working in polymers since I graduated from

—GUELCHER — DIRECT — WALLACE —

1 college, even while I was in college, so working with
2 different types of materials, polyesters, polyurethanes, a
3 number of different polymers over 20-plus years.

4 Q. What is a polymer?

5 A. So, a polymer is -- you might think of it in terms of a
6 plastic, so you think about the seats that you're sitting on
7 right now, they have a polyurethane foam inside. That's what
8 makes it more comfortable than a slab of wood. Your mattress
9 has a polyurethane foam. So, essentially, it's a plastic
10 material that, many cases, is typically derived from oil
11 chemicals, petrochemicals, that -- and you start with a very
12 small molecule and you grow it into a long one, and then the
13 properties of these polymers are very important, yeah.

14 Q. Does the work that you've done in this case concern
15 polymers?

16 A. Yes. Specifically, an active area of my research is how
17 the body responds to polymers. If you place a polymer in the
18 body, what does it do? Do you want it to go away, do you want
19 it to be stable? So a lot of my work focuses on how cells and
20 tissues in the body respond to polymers. And I certainly
21 think that this case falls within the scope of that question.

22 MR. WALLACE: Your Honor, at this time, plaintiffs
23 would offer Dr. Guelcher as an expert in the field of chemical
24 engineering and biomaterials.

25 THE COURT: Any voir dire?

—GUELCHER - DIRECT - WALLACE—

1 MR. THOMAS: No, Your Honor.

2 THE COURT: He may offer his opinions.

3 MR. WALLACE: Thank you, Your Honor.

4 BY MR. WALLACE:

5 Q. Before we get to those opinions, Dr. Guelcher, have you
6 been paid for the time that you've spent working on this case?

7 A. Yes, I have been.

8 Q. And how long have you been working on the issues of
9 polypropylene mesh?

10 A. I'd say at this point probably in the range of hundreds
11 of hours. I spent a lot of time reading many scientific
12 papers and documents.

13 Q. Can you tell us just approximately how many scientific
14 publications you've reviewed in the work that you've done in
15 polypropylene, if you know?

16 A. Probably exceeding 50, 60 papers, maybe more. There's a
17 lot.

18 MR. THOMAS: Your Honor, may we approach?

19 THE COURT: You may.

20 MR. THOMAS: Thank you.

21 THE COURT: Ladies and gentlemen, I forgot to tell
22 you, there will be occasions when we go to sidebar, just like
23 we did earlier today. When we do, you're not supposed to hear
24 what we're talking about so I turn on the sound machine, but I
25 ask you to talk among yourselves and be your own sound

—GUELCHER - DIRECT - WALLACE—

1 machine.

2 (The following occurred at sidebar.)

3 THE COURT: All right. Mr. Thomas.

4 MR. THOMAS: Thank you, Your Honor. Counsel, as the
5 Court is aware, has tendered us a PowerPoint presentation of
6 Dr. Guelcher's testimony.

7 THE COURT: Um-hum.

8 MR. THOMAS: Paragraph E is an opinion, more mesh
9 equals more foreign body response, which is not contained in
10 the summary of opinions in the expert report, and it's an
11 opinion that goes beyond both his expert report and the
12 depositions I took of Dr. Guelcher.

13 MR. WALLACE: I would only add, Your Honor, that he
14 filed a supplemental report shortly after that that addresses
15 the more-mesh concept which is on Page 2 of his supplemental
16 report --

17 MR. THOMAS: I thought the supplemental --

18 MR. WALLACE: -- which I will go get if you want me
19 to.

20 THE COURT: Let's see what he's got.

21 MR. WALLACE: But I can tell you -- I will just wait.

22 THE COURT: Wait.

23 MR. WALLACE: Thank you, sir.

24 MR. THOMAS: Your Honor, I brought the Court the
25 supplemental report of Dr. Guelcher, and Page 2 of the

—GUELCHER - DIRECT - WALLACE—

1 supplemental report has exactly the same opinions that are in
2 the original report.

3 MR. WALLACE: No, there is a -- let me get you the
4 right report, Dave. Let me go get the right report for him.

5 THE COURT: Get whatever report you have.

6 MR. WALLACE: More --

7 THE COURT: That's all right. It was represented
8 that he was not offering any new opinions on his supplemental
9 report when I was considering *Daubert* motions.

10 MR. WALLACE: Your Honor, this is a rebuttal report
11 that was done many, many, many months ago, not the matter that
12 you addressed. So --

13 THE COURT: So it either was or wasn't in the report.

14 MR. WALLACE: It is in the report, Your Honor. I can
15 point it to you and point it to Dave, if you'd like me to.

16 THE COURT: Why don't you two take a minute. I need
17 to know the sequence --

18 MR. WALLACE: Sure.

19 THE COURT: -- because when I was ruling on the
20 reports, as I recall, the -- the issue came up with regard to
21 whether he was offering any new reports in supplement -- any
22 new opinions in the supplement. And the answer I got from you
23 all was "no."

24 MR. WALLACE: And that is correct, Your Honor.

25 THE COURT: All right. Why don't you all talk about

—GUELCHER - DIRECT - WALLACE—

1 it, whatever this is.

2 MR. WALLACE: Sure.

3 (Discussion held off the record between Mr. Wallace
4 and Mr. Thomas.)

5 THE COURT: Yes, sir.

6 MR. THOMAS: Your Honor, I have spoken with
7 Mr. Wallace, and Dr. Guelcher did, in fact, supply a rebuttal
8 report to the expert reports of Ethicon. And we did file a
9 motion, a *Daubert* motion -- let me back up. The rebuttal
10 report does refer to Paragraph E, more mesh equals more
11 foreign body response. We moved on Dr. Guelcher and the Court
12 found in the order, I have the *Daubert* order if you'd like,
13 and limited Dr. Guelcher to the four opinions in the original
14 report --

15 THE COURT: I don't remember a reference to a
16 separate supplemental report. I remember -- give me that
17 sheet of paper.

18 MR. THOMAS: I have the *Daubert* order if the Court
19 likes.

20 THE COURT: Ethicon moved to exclude Dr. Guelcher's
21 testimony as it relates to supplemental reliance material
22 list. Did you go beyond that?

23 MR. THOMAS: That's a different motion -- no, Your
24 Honor. That was a motion -- they filed a supplemental
25 reliance list adding new documents, right before trial, that I

—GUELCHER - DIRECT - WALLACE—

1 hadn't had an opportunity to depose Dr. Guelcher on.

2 MR. WALLACE: Right.

3 MR. THOMAS: The Court denied that motion because
4 they were late-produced documents, as I recall the Court's
5 order. What I'm referring to is the *Daubert* motion that we
6 filed --

7 THE COURT: Let me see a copy of the opinion that you
8 are referring to.

9 (Pause.)

10 THE COURT: Show me. Show me where I limited
11 Dr. Guelcher's opinion. I don't recall doing that.

12 MR. THOMAS: Page 17 of the order, Your Honor.

13 THE COURT: Where is it that you moved to limit his
14 testimony about the opinion you're talking about?

15 MR. THOMAS: The opinion that he's talking about
16 here --

17 THE COURT: Where is it that you moved to limit that?
18 I don't remember that.

19 MR. THOMAS: I understood that was part of the
20 *Daubert* ruling, and the Court -- what I relied on is the Court
21 specifically laid out what the opinions were going to be. The
22 other alternative is this is not a true rebuttal opinion, but
23 we can get to that later.

24 THE COURT: What I'm trying to understand -- I'm
25 sorry. Did you object and raise an issue, when -- in your

—GUELCHER - DIRECT - WALLACE—

1 *Daubert* motions in this particular opinion and his
2 qualifications to offer it?

3 MR. THOMAS: I'm hesitant to represent that, Your
4 Honor, because it's been a long time since I looked at the
5 actual papers, to be honest with you, so I can't represent
6 that to the Court.

7 MR. WALLACE: Your Honor?

8 THE COURT: Yes.

9 MR. WALLACE: Your Honor, you asked a question about
10 the chronology, just so it's clear, and Mr. Thomas and I agree
11 on this, this rebuttal report was offered before
12 Dr. Guelcher's deposition was even taken the second time
13 around. So we hope that it's a nonissue, we can move through
14 quickly on the stand. In other words, he's been deposed. I
15 just want --

16 THE COURT: Was he cross-examined on that opinion?

17 MR. WALLACE: Well, there was lots of hours of
18 testimony by Mr. Thomas, from which Mr. Guelcher still --

19 THE COURT: He didn't testify, did he? I'm teasing.

20 (Laughter.)

21 THE COURT: Go ahead and finish your thought.

22 MR. WALLACE: No, I was just saying, Your Honor, and
23 Mr. Thomas agrees with this, we provided this rebuttal report,
24 Mr. Thomas and I agreed that even Mr. Guelcher can come back
25 and be deposed a second time, and Mr. Thomas and I mutually

—GUELCHER - DIRECT - WALLACE—

1 agreed, worked out the second deposition.

2 This was months and months before the *Daubert* motions
3 were ever filed, and so I would suggest that this opinion has
4 been out there. It's nothing new.

5 THE COURT: But it's not in his report.

6 MR. WALLACE: It is in his report, Your Honor. It is
7 in his expert rebuttal report that he filed which is the
8 subject of the --

9 THE COURT: Let's make it clear so the record is
10 clear.

11 MR. WALLACE: Thank you.

12 THE COURT: What is the objection?

13 MR. THOMAS: One, it's not in his original report.
14 When we moved on *Daubert* grounds to strike his testimony
15 entirely, for a number of reasons, the Court found these were
16 the four opinions which he was to express at trial. That's
17 what I --

18 THE COURT: To be clear, are you saying that he did
19 not offer this opinion before you made your motion?

20 MR. THOMAS: No, I'm not, Your Honor.

21 THE COURT: And did you move to say he wasn't
22 qualified to offer this opinion?

23 MR. THOMAS: I'm sure that I did, but I can't tell
24 you specifically that I did, Your Honor.

25 THE COURT: Well, I'll let the jury go take a break

—GUELCHER - DIRECT - WALLACE—

1 and you show me what you did.

2 MR. THOMAS: I'm not going to be able to put my hands
3 on it very quickly and I'm reluctant to take that much time
4 with the jury. I don't want to do that to the Court or --

5 MR. WALLACE: Dave, can I offer a suggestion?

6 MR. THOMAS: Sure.

7 THE COURT: Off the record.

8 (Discussion held off the record between Mr. Wallace
9 and Mr. Thomas.)

10 MR. THOMAS: Your Honor, I think we have reached an
11 accommodation on it.

12 THE COURT: Okay. Let's go.

13 (Sidebar concluded.)

14 THE COURT: Okay. Mr. Wallace?

15 MR. WALLACE: Can we move to the next slide. Let's
16 just go ahead and try to move ahead a little.

17 BY MR. WALLACE:

18 Q. Did you provide an expert report, a rebuttal report and
19 some reliance lists in this case?

20 A. Yes, I did.

21 Q. Okay. And in those documents, did you provide certain
22 opinions?

23 A. Yes, I did.

24 Q. Okay. And would you agree with me that the reports that
25 you filed and the rebuttal report you filed were much more

—GUELCHER — DIRECT — WALLACE —

1 extensive than what we have here represented on the slide?

2 A. Yes.

3 Q. Okay. Well, just to move forward, is this your summary
4 of opinions?

5 A. This is my summary of opinions.

6 Q. Okay. And, Dr. Guelcher, before we get to the summary of
7 your opinions, what I want to do is just establish some
8 definitions for the jury.

9 And I'm going to start with, Dr. Guelcher, what is
10 polypropylene?

11 A. So, polypropylene is a manmade or a synthetic material,
12 in a chemical plant. It's based on a petrochemical, and it's
13 produced in pellet form as shown in the picture there. And an
14 important point about this is that polypropylene is known to
15 be unstable, due to its molecular structure, the reactive
16 oxygen, and so, like many other products, antioxidants are
17 added to extend the service life of the polypropylene, to make
18 it last longer for the application it's designed for. That's
19 the purpose of the antioxidants.

20 Q. Can you tell the jury what -- some products that are made
21 with polypropylene?

22 A. Well, polypropylene parts are important in automotive
23 applications, toys, fishing line. It's a very well-known
24 industrial chemical that's used in a lot of applications.

25 Q. Let's go back to your summary opinion slide,

—GUELCHER - DIRECT - WALLACE—

1 Dr. Guelcher. It says, "Polypropylene plus oxygen equals
2 degradation." What do you mean by that?

3 A. So, polypropylene will react with oxygen and degrade.
4 This is known as an oxidation reaction. And that changes the
5 chemical structure of the polypropylene, is the most important
6 point. So, by reacting with the oxygen, its chemical
7 structure is changed. It's not stable.

8 Q. And I first want to talk about polypropylene outside of
9 the body.

10 A. Yes.

11 Q. Okay? So, when you're talking about polypropylene
12 reacting with oxygen equalling degradation, are you referring
13 to polypropylene outside of the body?

14 MR. THOMAS: Your Honor, objection, leading.

15 THE COURT: Sustained, but you can ask it directly
16 pretty easy.

17 BY MR. WALLACE:

18 Q. What happens to polypropylene out of the body?

19 A. Outside of the body, polypropylene can react with oxygen,
20 molecular oxygen just in the air that we breathe, O₂. This is
21 a faster reaction rate at higher temperatures, so in order to
22 make polypropylene useful, we saw the pellets. A pellet's not
23 very useful. So what you'll do is you'll heat it up and
24 either extrude it or mold it, but you have to heat it to high
25 temperatures in order to process it into a useful part. And

—GUELCHER — DIRECT — WALLACE —

1 these oxidation reactions can become very important at those
2 conditions.

3 Q. Let's just try to march through these, and then maybe
4 we'll come back to a few of them.

5 Number -- I'm sorry, Letter B, it says, "Antioxidants
6 can slow down degradation, but they cannot prevent it." What
7 do you mean by that?

8 A. So, this relates to the concept of a service life. So,
9 just about anything that you make or buy has a -- it's useful
10 for a certain period of time. Then it wears out. And the
11 same applies to plastics. And so antioxidants can slow this
12 degradation process, these chemical changes, for a period of
13 time, they can extend the service life, but they can't prevent
14 it forever. This process will continue, and eventually these
15 changes will happen. The question is when.

16 Q. When you talk about changes, are you talking about the
17 degradation process?

18 A. Yes. Changes to the structure of the molecule, of the
19 polypropylene.

20 Q. How long has this been known in the chemical field,
21 Dr. Guelcher?

22 A. Since the 1960s. When polyurethane -- polypropylene was
23 first invented, it was noticed that it had these degradation
24 problems, and that's when scientists started adding
25 antioxidants to make it last longer.

—GUELCHER — DIRECT — WALLACE —

1 Q. Let's move on to C. It says, "The body's natural defense
2 mechanism -- the foreign body response -- attacks the
3 polypropylene."

4 Let's take those one at a time. Dr. Guelcher, what are
5 you referring to when you say "the body's natural defense
6 mechanism"?

7 A. So, this is the response that your body has when a
8 foreign material is implanted, the material that your body
9 knows is not part of your body, and there's a defense
10 mechanism that the body has to deal with this to reject it or
11 to destroy it, and this is essentially the natural defense
12 mechanism.

13 Q. What do you mean by -- could you give us an explanation
14 of "foreign body response," or is that what you just --

15 A. So, the foreign body response or the foreign-body
16 reaction is a scientific term that's used to explain this
17 defense mechanism. So, there's a reaction that happens when a
18 foreign body is implanted at the cellular level, so this
19 happens actually to specific cells that attack the material.
20 That's what I'm referring to by the foreign body reaction.
21 It's just this natural defense mechanism.

22 Q. Dr. Guelcher, "attack" seems like a pretty strong word,
23 so could you explain that to the jury?

24 A. So, cells in your body, known as inflammatory cells,
25 these would be things like white blood cells, macrophages,

—GUELCHER — DIRECT — WALLACE —

1 foreign-body giant cells, these are inflammatory cells that
2 their job is to attack the foreign body.

3 A simple example would be a bacterial infection.

4 Bacteria is not supposed to be there, and so there's
5 specialized cells in the body that attack that and try to
6 destroy it so it doesn't harm the body. That's the response.

7 Q. Letter D says, "The foreign body response will not stop
8 until the mesh is removed." Do you see that?

9 A. Yes.

10 Q. And what do you mean by it?

11 A. So, the mesh is a foreign body. It -- it's not naturally
12 in your body. Like I said, it's a synthetic polymer that's
13 made in a chemical plant. It's planted in the body to
14 accomplish a certain purpose. And the body recognizes it as a
15 foreign material, and it will continue to attack it in this
16 way until it's removed or destroyed or it's gone.

17 Think of a splinter that you get in your finger. If
18 you never remove it, it over time will extrude. It's a simple
19 example, but that's the idea. It's ongoing until the foreign
20 body is gone.

21 Q. And you use the word "mesh." What are you referring to?

22 A. I'm referring to the polypropylene Prolene mesh that
23 we're discussing here today.

24 Q. When you say, "More mesh equals more foreign body
25 response," what do you mean?

—GUELCHER - DIRECT - WALLACE—

1 A. So, this is sort of a logical consequence of the other
2 opinions, in that if you have more mesh present -- this is
3 happening at the surface of the material, at the surface is
4 where it's happening. If you have more mesh, well, you're
5 going to have more response. It's going to be an elevated
6 response. More cells, more reactive oxygen, more -- it's an
7 elevated response, yeah.

8 Q. Well, you talked about more reactive oxygen and gave a
9 couple of other words that I think we're going to need to
10 define.

11 A. Yes.

12 Q. But why don't we try to go, just keeping moving through
13 it, and we'll come back to that.

14 Next slide. Keep going. Okay. What -- first of all,
15 before we get into the structure here, what are you trying to
16 explain to the jury?

17 A. So, this slide is explaining how this reaction that's
18 known as oxidation -- oxidation is a reaction with oxygen --
19 how this oxidation reaction alters the structure of
20 polypropylene. So you start off with the structure of
21 polypropylene, and you end up with something that's different.
22 That's the purpose of this slide.

23 Q. And so on the left, does that represent the chemical --

24 A. So --

25 Q. Let me -- excuse me, Doctor.

—GUELCHER — DIRECT — WALLACE—

1 A. I'm sorry.

2 Q. I'm sorry, let me finish.

3 Let me ask it this way: What is the box on the left?

4 A. Okay. So the molecule on the left is the structure of

5 polypropylene. That's a unit that repeats, so it's a very

6 long chain of these units. And the box in red, that's the

7 carbon-hydrogen tertiary bond. Why is it a tertiary bond?

8 Well, that carbon is bonded to other carbons, except for that

9 hydrogen. That's why it's a carbon-hydrogen tertiary bond.

10 So this is kind of the chemistry concept.

11 So -- and that bond is vulnerable to attack by the
12 oxygen. That's where the attack is happening. And there is a
13 series of reactions in this step that lead to changes in the
14 polypropylene structure, but that particular bond is the one
15 that reacts.

16 THE COURT: Hold just a second. It's not usual, just
17 so the jury knows, it's not usual for me to be showing you
18 things on here that the witness hasn't first tried to explain
19 or -- and I have a series of slides, it appears.

20 Have you had an opportunity to review them?

21 MR. THOMAS: I'm looking at them right now, Your
22 Honor.

23 THE COURT: What I want -- what I want to do is not
24 put them up until I see if there's an objection.

25 MR. WALLACE: Sure, Your Honor. I didn't realize --

—GUELCHER - DIRECT - WALLACE—

1 THE COURT: So before you get ready to go to your
2 next one, we'll see it.

3 MR. THOMAS: I have no objection to the next one,
4 Your Honor.

5 THE COURT: All right.

6 MR. WALLACE: Okay.

7 THE COURT: If we could just keep that process up, I
8 would appreciate it.

9 MR. WALLACE: And going forward, that will absolutely
10 be the case, Your Honor.

11 THE COURT: Thank you.

12 BY MR. WALLACE:

13 Q. When you said "vulnerable to attack," can you just tell
14 the jury what concept you're trying to explain?

15 A. There's a reaction between the oxygen and that bond.

16 Q. What's the next red box represent?

17 A. So, the next red box shows how that bond changes, so you
18 start off with this tertiary carbon-hydrogen bond. The next
19 red box shows that bond turn into what's called a
20 hydroperoxide bond, so it changes. Its chemical structure
21 changes. That's what's denoted there.

22 Q. When you say "chemical structure changes," you're saying
23 that the polypropylene actually changes because of oxidation
24 or something else?

25 A. Yes. It's a different molecule now, because you have

-GUELCHER - DIRECT - WALLACE

1 this hydroperoxide group instead of the hydrogen that's
2 changed.

3 Q. And we talked a little bit about antioxidants already.
4 But why don't we look at that second bullet point, where it
5 refers to structural changes. Can you tell the jury what
6 you're trying to say there?

7 A. So, these changes in the structure, for example, the
8 carbon-hydrogen bond going to a hydroperoxide bond, that could
9 be measured using analytical techniques such as spectroscopy,
10 so we could measure that, we can measure that change, and we
11 can also measure the change in the following reaction when it
12 goes to a carbonyl, which is the last red box. That's another
13 chemical change that we can measure by different analytical
14 changes.

15 Q. When you say "we," who are you referring to?

16 A. Scientists, engineers.

17 MR. WALLACE: Let's go to the next slide, please.

18 MR. THOMAS: That's fine.

19 MR. WALLACE: Okay. Thank you.

20 BY MR. WALLACE:

21 Q. You say at the top, "Implant materials selection." And
22 at the top you have "polypropylene," and then you have an
23 arrow. What do you mean?

24 A. So, this slide is showing several different types of
25 materials, and how easily they are oxidized or how easily this

—GUELCHER - DIRECT - WALLACE—

1 reaction with oxygen can occur. And so at the bottom, where
2 it says, "Difficult to oxidize," these are materials that
3 react very slowly with oxygen. For example, Teflon, Teflon
4 reacts slowly with oxygen.

5 Polypropylene, on the other hand, is one of the more
6 easily oxidized materials. So it's reacting much faster with
7 oxygen than a large number of other materials. It's much more
8 easily oxidized in that respect.

9 Q. How long have chemical scientists like yourself known
10 that polypropylene is easily oxidized?

11 A. This has been known for decades, I think. Since the
12 1960s, it was known that polypropylene is easily oxidized.

13 MR. WALLACE: Can you go to the next slide, please.

14 Dave --

15 MR. THOMAS: That's fine.

16 MR. WALLACE: Thank you.

17 BY MR. WALLACE:

18 Q. All right. You've talked a little bit about foreign body
19 reaction. You've got some photos here. Can you take us
20 through them?

21 A. So I mentioned the foreign-body reaction earlier. This
22 is the body's response to something that's implanted. It's
23 caused -- it's called the foreign-body reaction because that
24 refers specifically to the types of cells that respond. So
25 it's a reaction. You implant the material, and certain cells

—GUELCHER - DIRECT - WALLACE—

1 respond.

2 And so these are polyurethane films that were in the
3 body, and it shows the progression of this reaction. So in
4 the upper left-hand corner it says, "Monocytes, zero days," so
5 very quickly after an implantation of the device, or this
6 material, this foreign body, monocytes, which are very small
7 mononuclear cells, they have one nucleus, they attach to the
8 surface. They recognize it as a foreign body and they attach.
9 And that's what starts off this reaction.

10 Now, as you see the arrow there, it points to
11 macrophages at three days. Then these monocytes over a period
12 of several days change to form another cell called
13 "macrophage." And it's important to remember these cells are
14 attached to the surface. They're what we call an adherent
15 cell. They're attached to the surface of the material.

16 And then after about a week, some of these macrophages
17 will fuse. That means they join together to form a great big
18 cell that has multiple nuclei instead of just one, and then
19 finally, after about two weeks, that FBGC 14 days, those are
20 called foreign-body giant cells. That's just what they are,
21 they're giant cells, they're very large cells that have
22 multiple nuclei. And, again, all these cells are adherent to
23 the surface.

24 So, what happens at the surface is they're secreting
25 what's known as reactive oxygen species. And this is oxygen

—GUELCHER — DIRECT — WALLACE —

1 that's -- these are oxygen species that are much more reactive
2 than molecular oxygen, so they're much more potent. They
3 react faster. And that material surface is exposed to these
4 species. So it's exposed to these oxidizing agents.

5 This is what's known as the foreign-body reaction. But
6 it's driven by these types of cells that attach to the surface
7 and secrete reactive oxygen species with an aim to destroy the
8 material. That's why they're there. They want to remove this
9 material because it's a foreign body.

10 Q. Okay. So, if I understand you correctly, the monocytes
11 work with the macrophages to combine the foreign-body giant
12 cells and adhere to the surface of a foreign body; is that
13 right?

14 A. Yes, they're adherent, yes.

15 Q. All right. Going back to this "attack" word that you
16 used, is that what you're describing there?

17 A. This is the scientific explanation of the word "attack."
18 It's a chemical attack. It's, again, reactive oxygen species
19 or ROS.

20 Q. What are the -- what are these foreign-body giant cells
21 actually trying to do to the implant?

22 A. Well, they're trying to remove it from the body. That's
23 the response, to destroy it.

24 Q. What does ROS do in the body? What function does it
25 serve?

—GUELCHER — DIRECT — WALLACE —

1 A. So, much like if you take polypropylene and you heat it
2 in the air, your source of oxygen in the air is molecular
3 oxygen that we breathe, so if you heat it up, that molecular
4 oxygen in the air will react.

5 Well, in the body, it's a much lower temperature. So
6 you don't have this thermal oxidation, at high temperatures,
7 but the reactive oxygen species serves the same purpose.
8 They're much more reactive than oxygen at the body conditions,
9 and so they can cause these changes to polypropylene because
10 of their high reactivity.

11 Q. Dr. Guelcher, if I heard you correctly, are you offering
12 an opinion that reactive oxidative species is actually --
13 has -- is stronger than the oxygen --

14 MR. THOMAS: (Stands.)

15 THE COURT: Sustained.

16 BY MR. WALLACE:

17 Q. What effect -- let me ask this question: Does ROS have
18 an effect on polypropylene implanted in the human body?

19 A. Yes, it does, because polypropylene reacts with oxygen.
20 This is simply a much more potent form of oxygen, so it's a
21 similar reaction.

22 Q. Thank you.

23 And how long has the foreign-body reaction been
24 understood by scientists and biomedical engineers like
25 yourself?

—GUELCHER - DIRECT - WALLACE—

1 A. So, this was discovered in the early 1990s in a few very
2 important papers. It was discovered that the failure of
3 certain biomaterials could be traced in this foreign-body
4 reaction. So materials that were thought to be safe, such as
5 insulation and cardiac pacemaker leads, thought to be safe,
6 but in the early 1990s, we realized that, in fact, it wasn't
7 because this foreign-body reaction was causing it to degrade.
8 That's what -- so it was in the early '90s.

9 MR. THOMAS: This is the polyurethane slide?

10 MR. WALLACE: Okay.

11 MR. THOMAS: Yes.

12 MR. WALLACE: Okay. We'll just go to the next slide.

13 BY MR. WALLACE:

14 Q. Can you describe to the jury what you have done with this
15 slide? And can I withdraw the question and ask you a
16 different one?

17 Did you actually create this slide yourself?

18 A. Yes, I did.

19 Q. Okay. So, tell the jury what you're trying to explain
20 there.

21 A. So, I spent some time talking about the foreign-body
22 reaction. And this happens no matter what you implant. Even
23 it can happen with other types of dead tissue. It -- it
24 happens with anything you implant into the body.

25 The important question as an engineer, someone

—GUELCHER - DIRECT - WALLACE—

1 designing a material, is: How is the material that I'm
2 implanting going to respond to that foreign body reaction?
3 That's something I can control, as an engineer, and it's a
4 very important question.

5 So, here I'm using the example of the
6 poly(ether)urethane pacemaker lead to explain this point.

7 And so these were, again, materials that were believed
8 to be safe, and then some patients started having problems and
9 the leads were taken out of the body or explanted, and some
10 studies were done, and it was shown that the combination of
11 chemical degradation that results from the foreign-body
12 reaction, that's the reactive oxygen, causes chemical
13 degradation, just like I explained for polypropylene. That
14 combined with physical damage such as cracking, in response to
15 this, embrittlement, led to device failure in a number of
16 patients, so it can be a very serious problem. And it doesn't
17 stop until the device is removed. And this has led to the
18 discovery of replacing materials for this application.

19 So, in this little chart here, I tried to show what I
20 consider to be really a vicious cycle of this problem. So if
21 you look at the bottom, when the device is implanted, you have
22 this infiltration of inflammatory cells, that's at the bottom.
23 And that happens once the device is implanted. So you get
24 these cells that attach to the surface, and then oxidation,
25 that's in response to the reactive oxygen secreted by the

—GUELCHER — DIRECT — WALLACE —

1 cells.

2 So, now we have oxidation of the material or reaction,
3 it's changing, it becomes embrittled. This can result in loss
4 of flexibility, cracking, which leads to more exposed surface.
5 So this reaction starts at the surface and it keeps going down
6 into the bulk of the material, can result in mechanical
7 failure. So this is the effect that the foreign-body reaction
8 can have on an implant that's not resistant, that's not --
9 that is susceptible to reaction with oxygen. That's what's
10 summarized in this slide.

11 Q. Dr. Guelcher, have you -- are you aware of any instance
12 where degradation might be desired in an implant?

13 A. So, in my own research at Vanderbilt, these are some
14 papers we published just in the past few years. And we're
15 interested in a different problem, that is, if I have a bone
16 void and it's not healing, can I put a scaffold in there or a
17 graft that will help it to heal. In other words, it won't
18 heal because there is a large hole, but if I put a structure
19 that has a scaffold to it, cells can migrate in and heal it.

20 Now, in this application, we want that scaffold to go
21 away once the wound is healed, but it's very important that we
22 control the rate at which it goes away. So we've actually
23 designed materials that respond to this foreign-body reaction,
24 in other words, they are designed to go away once cells start
25 to cause a new matrix, they degrade the scaffold, and the end

—GUELCHER - DIRECT - WALLACE—

1 result of this process is you have a healed wound.

2 So we're actually using this foreign-body reaction to
3 design new materials that will improve healing. That's quite
4 different from the polypropylene case where you want it to be
5 stable. That's a very different application. But my point is
6 that we can -- as an engineer, we can actually design
7 materials that respond to this foreign-body reaction, to
8 accomplish healing. That's the work that I'm doing now.

9 Q. I want to make sure I've heard you correctly, going back
10 to whether or not the process ever stops. Is there any time
11 that the reactive oxidative species will stop attacking the
12 mesh?

13 MR. THOMAS: Asked and answered, Your Honor.

14 THE COURT: Sustained.

15 BY MR. WALLACE:

16 Q. Does polypropylene degrade inside the human body?

17 A. Yes, it does.

18 Q. Can you explain that to the jury?

19 A. It's the same process of attachment of inflammatory cells
20 that then secrete reactive oxygen, the polypropylene reacts
21 with that oxygen, and the composition changes.

22 Q. When you use the word "embrittlement," what do you mean?

23 A. So, "embrittlement" is a technical term that refers to
24 the transition from a plastic that starts off being very
25 compliant or stretchy, you can pull on it like a rubber band,

—GUELCHER - DIRECT - WALLACE—

1 and it becomes more brittle, so it's -- then it's like a hard,
2 rigid plastic. It's hard, it's rigid, it cracks. That's what
3 we mean by "embrittlement."

4 Q. Do you have an opinion on whether polypropylene becomes
5 embrittled inside the human body?

6 A. Yes. So, the consequence of this response to the
7 foreign-body reaction is embrittlement. That's one
8 consequence, that's one response.

9 Q. Do you have an opinion on whether polypropylene suffers
10 from a loss of flexibility inside the human body as a result
11 of embrittlement?

12 A. Yes. So, loss of flexibility would happen when it
13 becomes brittle. It's no longer compliant or stretchable.

14 Q. We talked earlier about antioxidants.

15 MR. WALLACE: Can we go to the next slide?

16 MR. THOMAS: Yes.

17 BY MR. WALLACE:

18 Q. Can you explain to the jury the reason for this slide?

19 A. So, as I mentioned before, because of the susceptibility
20 of reactivity of polypropylene with oxygen, we have to add
21 antioxidants. And these are typically packaged as primary and
22 secondary antioxidants, and this technology, again, was worked
23 out largely in the 1960s.

24 So, what do I mean by "primary" and "secondary"? Well,
25 a primary antioxidant is one that is intended to protect it

—GUELCHER — DIRECT — WALLACE —

1 while it's being processed at high temperatures. So you have
2 a pellet, and you want to make something useful out of the
3 pellet. You have to heat it up and remold it. This requires
4 high temperatures, and so these antioxidants are designed to
5 protect while it's being processed at high temperatures, and
6 some of them are expended, at this time. They're consumed,
7 they're used up.

8 Now, a secondary oxidant essentially enhances the
9 primary one. It's intended to improve long-term storage.
10 It's intended to protect against ultraviolet light. So
11 different antioxidants do different things and they're used in
12 combinations that have an overall good effect to stabilize it.

13 Q. Why is that important to you, as an expert in biomedical
14 and chemical engineering in this case?

15 A. Well, the question that I would have is these
16 antioxidants are designed to protect during processing and
17 during long-term use, exposure for several years to summers in
18 Tennessee, for example, but they're not optimized to protect
19 polypropylene against this reactive oxygen *in vivo*.

20 Q. Dr. Guelcher, can I interrupt you there?

21 A. Yes.

22 Q. What do you mean by that?

23 A. Well, they are not designed or they not intended to
24 protect polypropylene against this reactive oxygen, against
25 this foreign-body reaction.

—GUELCHER - DIRECT - WALLACE—

1 Q. What do you mean by "intended"?

2 MR. THOMAS: Objection, Your Honor, testifying to the
3 state of mind of Ethicon.

4 MR. WALLACE: I'm not talking about Ethicon, Your
5 Honor. I'm asking --

6 THE COURT: Overruled. Go ahead.

7 THE WITNESS: So the purpose of the antioxidant is to
8 protect against processing at thermal -- sorry -- processing
9 at higher temperatures, long-term exposure to atmospheric
10 oxygen that we breathe. Its purpose is not to protect against
11 reactive oxygen in vivo. It's not possible because the
12 reactive oxygen, foreign-body reaction, wasn't discovered
13 until 1990.

14 So these antioxidant packages, when they were
15 created, they simply didn't know about the foreign-body
16 reaction, so this wasn't taken into account when they were
17 designed.

18 BY MR. WALLACE:

19 Q. Do you know whether or not -- well, why is that important
20 to the TTVT-O device?

21 A. Well, because it's -- it's not guaranteed that these
22 antioxidants are going to protect against the reactive oxygen
23 in the body. It's not been studied. It wasn't looked at. It
24 wasn't taken into account when these devices were designed.

25 Q. Do you know whether or not the Prolene mesh that is the

—GUELCHER — DIRECT — WALLACE —

1 TVT-O mesh, do you know whether or not that has an antioxidant
2 package added to it?

3 A. So, Prolene has this package of secondary anti- --
4 primary and secondary antioxidants. It has a primary
5 antioxidant, this is what's referred to as a hindered phenolic
6 compound. What that means is it reacts with free radicals,
7 and it doesn't evaporate when you heat it to high
8 temperatures, it stays in the material, it doesn't evaporate
9 into the air.

10 It also has a secondary antioxidant which is a typical
11 one that's used. This is a thioester and, again, this is
12 intended to improve long-term storage at atmospheric
13 conditions, not in the body, but atmospheric conditions.

14 Q. Do you have an opinion on whether the antioxidant package
15 that is added to the Prolene mesh that is the TVT-O stops
16 degradation?

17 MR. THOMAS: Objection, Your Honor. Sidebar, please.

18 THE COURT: Hold just one second.

19 All right. Let's see you at sidebar.

20 (The following occurred at sidebar.)

21 MR. THOMAS: Your Honor, Ethicon objects to the
22 question as phrased because not only is it an opinion that is
23 not expressed in the four, now five, which he's been permitted
24 to testify, but he has not done any testing and analysis with
25 respect to Prolene specifically to give an opinion about the

—GUELCHER - DIRECT - WALLACE—

1 extent to which the antioxidants in Prolene would deplete over
2 time and lead to degradation.

3 MR. WALLACE: Your Honor, if I were to respond, I
4 would say it would be comprised within Opinion 1, and
5 Mr. Guelcher, as I understand it, has been extensively
6 questioned by Mr. Thomas on the antioxidant issue here in
7 connection with his opinion about 1.

8 THE COURT: Excuse me.

9 (Pause.)

10 THE COURT: It is not listed precisely, but it was
11 explained by you and included in the opinion. There was an
12 extensive explanation about the evidence. What's your point?
13 I'm sorry.

14 MR. THOMAS: I'm trying to understand the ruling.
15 The witness has not done any testing to determine the extent
16 to which the antioxidants may deplete over time.

17 THE COURT: He has not and he is not --

18 MR. THOMAS: (Indicating.)

19 THE COURT: Don't shush me.

20 MR. THOMAS: I'm sorry. That's a mannerism, not a
21 shush. I apologize.

22 THE COURT: He has not. I didn't understand the
23 question to be, had he done testing. Was that the question?

24 MR. THOMAS: That's the objection, to him giving that
25 opinion as phrased because there is no basis in science or no

—GUELCHER — DIRECT — WALLACE —

1 testing to say, to a reasonable degree of certainty, that the
2 Prolene, polypropylene mesh, leaches antioxidants or depletes
3 antioxidants over time so it would degrade.

4 THE COURT: I'm going to allow him to testify and be
5 subject to cross-examination.

6 MR. WALLACE: Thank you, Judge.

7 (Sidebar concluded.)

8 BY MR. WALLACE:

9 Q. Dr. Guelcher, with the indulgence of counsel, I just want
10 to go back and reorient us to where we were. We were talking
11 about the polypropylene antioxidants that are added during the
12 manufacturing process to the Prolene mesh. Is that correct?

13 A. That's right.

14 Q. Okay. And, just to get us back to where we were, you
15 said that, if I'm correct, you had an opinion on whether or
16 not those antioxidants that are added to the Prolene mesh
17 stopped the mesh from degrading. Is that right?

18 A. Yes.

19 Q. Okay. Can you explain why it is, why is it your opinion
20 that the antioxidant package that's added to the Prolene mesh,
21 that is ultimately made into the TVT-O, does not stop
22 degradation?

23 A. Well, I've seen evidence that Prolene sutures undergo
24 this reaction with oxygen and showed evidence of surface
25 cracking. Based on that evidence that I've seen, I don't

—GUELCHER - DIRECT - WALLACE—

1 believe these antioxidant packages stabilize polypropylene
2 against ROS in vivo, in the body.

3 Q. And what specifically -- what evidence are you
4 specifically referring to?

5 A. There were -- there are two studies that I've reviewed.
6 One was a study in dogs where these sutures were followed up
7 to seven years, and the other is studies of sutures that were
8 explanted from human patients for up to eight years. That's
9 the evidence.

10 MR. WALLACE: 2026, Dave.

11 MR. THOMAS: Do you have a copy for me?

12 MR. WALLACE: I'm sorry.

13 MR. THOMAS: Thank you.

14 MR. WALLACE: Your Honor, I was able to talk to
15 Mr. Thomas during the break about the four documents we'll be
16 referencing.

17 THE COURT: Yes.

18 BY MR. WALLACE:

19 Q. So, Dr. Guelcher, you've -- do you have Exhibit 2026 in
20 front of you?

21 A. Yes.

22 Q. Okay.

23 MR. WALLACE: Dave -- I'm sorry, counsel, do you have
24 it?

25 MR. THOMAS: I do, thank you.

—GUELCHER — DIRECT — WALLACE—

1 MR. WALLACE: Okay.

2 BY MR. WALLACE:

3 Q. Is this one of the studies that you're referring to?

4 A. Yes.

5 MR. WALLACE: Your Honor, may I publish it on the
6 screen?

7 THE COURT: Do you want to move its admission?

8 MR. WALLACE: Well --

9 MR. THOMAS: I have no objection, Your Honor.

10 THE COURT: It may be received.

11 MR. WALLACE: Thank you, Your Honor.

12 (PLAINTIFFS' EXHIBIT P-2026 WAS RECEIVED IN EVIDENCE.)

13 THE COURT: Make sure that the paper copy is provided
14 to the Courtroom Deputy -- after. You don't have to do it
15 this minute. But just be sure.

16 MR. WALLACE: Thank you.

17 BY MR. WALLACE:

18 Q. And what is in front of you, Dr. Guelcher?

19 A. So, this is a document explaining the analysis of Prolene
20 sutures that were explanted from humans.

21 Q. And if you look at the top of the left-hand page, where
22 it says, "IR microscopy of explanted Prolene." Do you see
23 that?

24 A. Yes.

25 Q. In your review of this study, what does that mean to you?

—GUELCHER — DIRECT — WALLACE—

1 A. So, IR is infrared, spectroscopy, and infrared
2 spectroscopy is useful for identifying specific chemical bonds
3 in the material, so it tells us what bonds are there. And
4 this is a spectroscopy technique that's used to assess that.

5 Q. And do you know whether or not this is an Ethicon study?

6 A. Yes, it has Ethicon letterhead on it, so this was --

7 Q. And do you -- do you know the date that this document was
8 published?

9 A. So it's September 30th, 1987.

10 MR. WALLACE: Can you pull that up and also the
11 "Samples" paragraph at the top?

12 BY MR. WALLACE:

13 Q. When you said that it was a human -- that it came from a
14 human, if you can look at that language and explain to the
15 jury what they're seeing.

16 A. So, this is a human vascular graft, that's a blood vessel
17 graft, that was explanted -- that means it was taken out of a
18 human -- by this Professor Guidoin in Quebec, I believe, and
19 examined by IR spectroscopy.

20 Q. And if you could go to Page 2 and look at the
21 conclusions, please.

22 Tell us, Dr. Guelcher, what you found significant about
23 the conclusions in this Ethicon study.

24 A. So, the first conclusion states that the amount of DLTD_P,
25 that's a secondary antioxidant -- that's the secondary

-GUELCHER - DIRECT - WALLACE -

1 antioxidant that's used in Prolene -- is reduced in the
2 explanted sutures. So no DLTD is observed in the surface
3 scrapes, so there were cracks on these regions that they
4 scraped. They didn't see --

5 Q. Can we stop there for a second --

6 A. Yes.

7 Q. -- so we can take it one step at a time, Dr. Guelcher.

8 When you say "DLTD," are you referring to the
9 antioxidant?

10 A. Yes, that's the antioxidant.

11 Q. And can you explain in practical terms what the
12 significance of this conclusion is as it relates to your
13 opinions?

14 A. Well, the way I interpret this statement is there are
15 cracked regions, so, again, this foreign-body reaction can
16 lead to cracking, embrittlement, because brittle things crack.
17 These cracked regions show no evidence of this stabilizer, so
18 that means that the stabilizer is expended, it was used. It
19 was used up in this region. And once it's used up, there's
20 nothing to protect the polypropylene from reacting. So it
21 tells me that the antioxidant in this cracked region was
22 consumed and that the polypropylene had oxidized. This is
23 what this tells me.

24 THE COURT: May I interrupt just a second? This is
25 1987. I thought you said they didn't figure this out until

—GUELCHER — DIRECT — WALLACE—

1 the '90s.

2 THE WITNESS: Well, sir, I meant that the
3 foreign-body reaction wasn't discovered until the '90s, but
4 this was an observation that was made independent of that
5 discovery.

6 THE COURT: What's the difference?

7 THE WITNESS: Well, so the discovery in 1990 was why
8 this happens. So there were a number of observations in the
9 '70s and '80s that this was happening. And it wasn't until
10 the 1990s where it was explained on sort of a cell and
11 molecular level what exactly was happening. This is an
12 observation.

13 THE COURT: Proceed.

14 MR. WALLACE: Thank you, Your Honor.

15 BY MR. WALLACE:

16 Q. With respect to Conclusion Number 2, what is the
17 significance of Conclusion Number 2 to your opinion of -- on
18 whether or not the antioxidants stop the degradation process?

19 A. Well, I think Number 2 is consistent with Number 1, in
20 that these cracks cannot be attributed to protein or tissue
21 that's sticking to the material. It's not material from the
22 body. It's cracked polypropylene, oxidized polypropylene. So
23 this is consistent with the notion that the antioxidant was
24 consumed and the polypropylene had reacted.

25 Q. What -- with respect to the word "protein" in these kinds

—GUELCHER — DIRECT — WALLACE —

1 of studies, what are they referring to?

2 A. Well, protein would be -- it's a component of tissue. So
3 tissue from the body, this is essentially, in my
4 interpretation, saying that there's no tissue that's stuck to
5 these sutures. It was successfully cleaned, and what you're
6 looking at is the polypropylene. You're not looking at tissue
7 that's stuck.

8 Q. Thank you.

9 Can we just move to 3 then, please.

10 What's the significance of Conclusion Number 3 to your
11 opinion, Dr. Guelcher?

12 A. So, Statement Number 3 is again saying there are these
13 cracked regions of the suture, where we see cracking, that was
14 scraped off, and that scraped-off material that had cracked,
15 they did an experiment to measure at what temperature does it
16 melt. So we know that pure polypropylene melts at a certain
17 temperature, and this material melted at a temperature below
18 that, so that's a change in the melting temperature. That
19 tells us there's a change in the polypropylene because pure
20 polypropylene melts at a specific temperature just like, you
21 know, ice melts at zero degrees, you know, zero degrees
22 Celsius. Ice melts at a defined temperature.

23 In the same sense, polypropylene melts at a very
24 defined temperature as determined by the structure, and if
25 that structure changes, the melting temperature will change,

—GUELCHER — DIRECT — WALLACE—

1 and that's what was seen here. So there's a change in the
2 melting temperature that's consistent with this notion that it
3 oxidized and changed.

4 Q. What effect, if any, does Paragraph Number 4 have on your
5 opinions?

6 A. Well, I find Paragraph Number 4 to be a subjective
7 statement. Again, this reaction starts at the surface and
8 works its way down. And some of the cracks -- I mean, again,
9 it's happening at the surface, and to say that it's only a
10 minor portion of the entire suture, I think that needs to be
11 tested further.

12 Q. Do you know whether or not there were any images taken of
13 these -- of this polypropylene?

14 A. From my understanding, there were, yes.

15 THE COURT: Where did you get that idea?

16 THE WITNESS: From the report.

17 THE COURT: All right.

18 THE WITNESS: Sorry. I'll be more direct.

19 THE COURT: I was just trying to see if there was a
20 foundation to be laid here.

21 MR. WALLACE: Sure. 2026, any objection, Dave?

22 MR. THOMAS: Yeah, there is. I need to approach with
23 counsel on this.

24 THE COURT: Okay.

25 MR. WALLACE: We'll try to work it out ourselves.

-GUELCHER - DIRECT - WALLACE-

1 THE COURT: All right. 2026, when it's finished --
2 go ahead and bring her 2026 so we won't get behind here. All
3 of this has been about 2026.

4 MR. WALLACE: Thank you.

5 THE COURT: Got it worked out?

6 MR. WALLACE: I hope so. I believe so.

7 THE COURT: All right.

8 MR. THOMAS: That's my -- I'm sorry.

9 THE COURT: I'm sorry.

10 MR. THOMAS: That's my copy, I think you took.

11 (Laughter.)

12 MR. THOMAS: Got to have a program.

13 THE COURT: All right, Mr. Wallace.

14 BY MR. WALLACE:

15 Q. Dr. Guelcher, I made a mistake. When I spoke about the
16 SEM image, images that you might have seen, I linked them to
17 this human study. So I'm going to make my question really
18 simple and very clear for the record.

19 Have you seen any Ethicon documents where there are SEM
20 images of Prolene explants?

21 A. Yes.

22 Q. Okay.

23 MR. WALLACE: 14461 is the exhibit I'd like to offer,
24 Your Honor, and move it into evidence at the conclusion of the
25 case, absent counsel's position on it.

—GUELCHER — DIRECT — WALLACE —

1 MR. THOMAS: Your Honor, these are just kind of SEM
2 images in the air. They're not tied to anything. They're
3 scanning electronic microscopy images that aren't tied to
4 anything, and I don't think there's an adequate foundation for
5 them to be --

6 THE COURT: This time I have to sustain the
7 objection.

8 MR. WALLACE: That's fine. Thank you, Your Honor.

9 BY MR. WALLACE:

10 Q. You mentioned a dog study. Can you tell me whether or
11 not you reviewed any Ethicon documents relating to a dog study
12 and whether -- I will just leave it there.

13 A. Yes, I did.

14 Q. Okay. And did you review those documents in connection
15 with reaching your opinions in this case?

16 A. Yes, I did.

17 MR. WALLACE: 13152 would be the exhibit I'd like to
18 offer, Your Honor, absent an objection.

19 THE COURT: Is there an objection?

20 MR. THOMAS: No, Your Honor.

21 THE COURT: It may be received.

22 MR. WALLACE: Thank you, Your Honor.

23 (PLAINTIFFS' EXHIBIT P-13152 WAS RECEIVED IN EVIDENCE.)

24 THE COURT: Make sure there's a paper copy provided
25 to the Courtroom Deputy.

—GUELCHER — DIRECT — WALLACE—

1 MR. WALLACE: Can we pull up --

2 THE COURT: And provide it to the Courtroom Deputy.

3 BY MR. WALLACE:

4 Q. Can you please -- do you have it in front of you,
5 Dr. Guelcher?

6 A. Yes.

7 Q. Can you tell the jury what the document you have in front
8 of you is and the document that they have on the screen in
9 front of them?

10 A. So this is titled "Seven-Year Data for a Ten-Year Prolene
11 Study."

12 Q. And what is the date of that?

13 A. October 15th, 1992.

14 Q. And, in reviewing this document in connection with the
15 work that did you in this case, what conclusions did you draw?

16 A. Well, this document, again, showed evidence that the
17 polypropylene was changing and cracking on the surface of the
18 suture, that the Prolene suture was changing with time and
19 cracking.

20 Q. In the interest of time, Dr. Guelcher, I want you to look
21 at the conclusions that are found on the second page in the
22 middle of the document.

23 A. Yes.

24 Q. And I'm just going to take those, again, one at a time.

25 Can you -- and you have reviewed the entirety of this

—GUELCHER — DIRECT — WALLACE —

1 document?

2 A. Yes. It's very long. Yes.

3 Q. Can you tell me what impact that first bullet point
4 that's the conclusion there had on your opinions in this case?

5 A. The seven-year in vivo results generally substantiated
6 the five-year findings. They closely correspond to the
7 observations of the explanted sutures of the dog that died
8 prematurely, and these findings were that the Prolene was
9 cracking with time and that was increasing with time.

10 Q. I'd like just -- just to take a step back and give the
11 jury a little bit of context for this study. What do you
12 understand the study, this study to be about and how long it
13 went?

14 A. So, from my reading of the document, this study was
15 designed to be a ten-year study in dogs, to understand the
16 stability of the Prolene suture. So what happens -- how does
17 the Prolene suture change over time, and it's implanted in a
18 dog because this is -- we can do this in animals. You can't
19 do these type of experiments in humans, and the dog is a good
20 model, it's a large animal model. And so we can use these
21 data to tell us something about how Prolene sutures would
22 respond and how stable they are, how they'll react in a human.

23 And, again, it was designed to be a ten-year study.
24 One of the dogs died prematurely, not related to the suture,
25 at six years and ten-and-a-half months, and so they sacrificed

—GUELCHER - DIRECT - WALLACE—

1 all the dogs at seven years so they could get the data.

2 That's my understanding.

3 Q. And let's move on to the second bullet point. Tell me
4 what, if anything, this second conclusion -- what impact, if
5 any, it had on your opinions.

6 A. So the second conclusion states that degradation in
7 Prolene is still increasing, and PVDF, which is another
8 material that is less susceptible, so it's less reactive with
9 oxygen, PVDF was more stable, in terms of cracking. So my --
10 what I learned from this was that, with the increased time,
11 the degradation of Prolene is continuing. This is consistent
12 with the idea that the foreign-body reaction doesn't stop. It
13 just keeps going until the material is removed.

14 Q. Can you move on to the third conclusion and tell the
15 jury, what, if any, impact that had on your opinions in this
16 case?

17 A. Well, this is, again, noting that this reaction starts at
18 the surface, so the eight explanted Ethilon sutures all showed
19 heavy cracking, in many cases abrasion of the dyed surface
20 layer. A decrease in the suture diameter was apparent in
21 several cases. So Ethilon is a different type of material.
22 It was also degrading. And they noticed a decrease in the
23 diameter of the suture which, again, is consistent with this
24 idea that it starts at the surface and works its way in, until
25 you're gradually losing material until it works its way to the

—GUELCHER — DIRECT — WALLACE —

1 middle of the suture.

2 Q. Just a point of clarification, Dr. Guelcher. Are --

3 PVDF, that's not Prolene, is it?

4 A. No, that's a different material. That's polyvinylidene
5 fluoride. That's chemically different from polypropylene.

6 Q. Thank you.

7 Let's just move right on to the fourth bullet point.
8 And tell the jury what impact, if any, that had on your
9 opinions in this case.

10 A. Well, in this other type of material, they did not find
11 any cracks. There were some scratches. What this tells me,
12 that these four materials that they implanted were all
13 degrading at different rates. Some of them were more affected
14 by the reactive oxygen than others.

15 Q. Is Novafil polypropylene?

16 A. No.

17 Q. How -- how have the human Prolene suture study and this
18 dog study, how have they impacted your opinions on mesh, if at
19 all?

20 A. So, both the human explants that were explanted from
21 humans out to eight years and the seven-year dog study both
22 show that the polypropylene, the Prolene polypropylene, reacts
23 with the oxygen that's secreted by these inflammatory cells
24 and it changes the structure over time. So, as we progress
25 from one to five, seven, eight years, these changes get more

—GUELCHER - DIRECT - WALLACE—

1 severe, we see more cracking, more oxidation, more changes in
2 the properties of the polypropylene.

3 This is basically happening because of this
4 foreign-body reaction. And, in my opinion, these changes,
5 because the mesh is also made from propylene, this reaction
6 with oxygen, these changes in the surface will also occur with
7 the mesh because it's made from the same base material,
8 propylene.

9 Q. So, I'll try to ask it this way, Dr. Guelcher. Does the
10 fact that this is a Prolene suture affect at all your opinion
11 on what you referred to as the more-mesh opinion?

12 A. So, I think it's very important to remember that a suture
13 implanted under the skin or in a blood vessel is very
14 different than mesh implanted in the pelvic floor. Mesh has a
15 lot more polypropylene, a lot more Prolene, a lot more
16 surface, that can react with this oxygen.

17 So, I think what we can learn from the suture study is
18 that the Prolene is unstable and it reacts in the body.
19 Whether -- in this -- in my view, would lead to more studies
20 with the mesh actually in the anatomic location where I want
21 to use it, in the pelvic floor.

22 How does this oxidation affect the mesh in the pelvic
23 floor? This is, to me, an important unanswered question. But
24 what these studies point to is that Prolene does change over
25 time. That's my conclusion.

—GUELCHER — DIRECT — WALLACE —

1 Q. Well, since we're talking about Ethicon documents, beyond
2 the documents that the jury has seen and that have been
3 offered into evidence, did you review any other Ethicon
4 documents?

5 A. I reviewed a number of other Ethicon documents. These
6 are the two that struck me as the most -- in forming my
7 opinions.

8 Q. And in reviewing those Ethicon documents, did you see any
9 other studies like these that were actually done on the TTV-T-O
10 mesh or mesh of any kind?

11 A. There are a number of other studies looking at mesh,
12 complications of mesh, and what happens to mesh when it's
13 implanted in the body.

14 Q. Well, my question is more specific than that,
15 Dr. Guelcher.

16 My question is, specifically, in all of the internal
17 company documents that you reviewed, did you see whether or
18 not Ethicon ever did any sort of explant studies on their
19 mesh?

20 A. I haven't seen those documents, no.

21 Q. Is that at all important to you as a biomedical engineer
22 and how it might impact your opinions in this case?

23 MR. THOMAS: Objection, Your Honor.

24 THE COURT: Sustained.

25 BY MR. WALLACE:

—GUELCHER - DIRECT - WALLACE—

1 Q. Now, when you looked at these Ethicon documents, who
2 provided those to you?

3 MR. THOMAS: I'm going to object to the generic
4 description of documents. I really don't know what he's
5 talking about. I don't think the witness does either.

6 THE COURT: Sustained. The documents that have been
7 admitted into evidence, you may inquire about certainly.

8 MR. WALLACE: Thank you.

9 THE COURT: I'm not trying to limit you. I'm just
10 trying to hurry it.

11 MR. WALLACE: Okay. Sure. Then why don't I move on.

12 BY MR. WALLACE:

13 Q. Did you -- in connection with the work that you've done
14 on polypropylene, have you reviewed any literature?

15 A. Yes. There is a number of published papers on these
16 meshes and how they respond.

17 Q. In connection -- are you familiar with Drs. Costello and
18 Clavé?

19 A. Yes.

20 Q. Have you reviewed their work?

21 A. Yes, I have.

22 Q. Can you tell the jury -- can we go to the --

23 MR. THOMAS: Before you publish anything, may I have
24 a copy of whatever you're going to publish?

25 MR. WALLACE: It's in the PowerPoint.

-GUELCHER - DIRECT - WALLACE-

1 MR. THOMAS: Well, it's quotes from the study. I
2 object to this, isolated quotes from the study, Your Honor, as
3 opposed to the full study.

4 THE COURT: Do you have a copy of the full study that
5 you can provide counsel? If that's what you plan to
6 introduce.

7 MR. WALLACE: It's just the articles. They're marked
8 as exhibits. I'll give you the exhibit numbers, David. I
9 believe you have a copy in front of you.

10 THE COURT: Why don't you two get together.

11 MR. WALLACE: Sure.

12 THE COURT: Maybe over that way a little bit.

13 (Discussion held off the record between Mr. Wallace
14 and Mr. Thomas.)

15 MR. WALLACE: Your Honor, may I proceed?

16 THE COURT: You may.

17 MR. WALLACE: And, Mr. Thomas, you have the article.

18 BY MR. WALLACE:

19 Q. In connection with your work, did you perform a
20 literature search?

21 A. Yes, I did. I searched a number of papers on this.

22 Q. And in connection with your work, did you come across any
23 articles that dealt with polypropylene degradation in
24 explants?

25 A. Yes, I did.

—GUELCHER - DIRECT - WALLACE—

1 Q. And what articles were those?

2 A. Well, I've selected three that I believe make the point,
3 by Clavé, et al., and published in 2009; by Costello, et al.,
4 published in 2007; and by Wood, et al., published in 2013.

5 Q. And, for the record, the Clavé article is Exhibit 21457.

6 A. Yes, that's right.

7 MR. WALLACE: And absent an objection, I'd like to be
8 able to publish it to the jury.

9 THE COURT: 21 -- the number is?

10 MR. WALLACE: 21457.

11 THE COURT: 21457 may be admitted when presented to
12 the Courtroom Deputy.

13 (PLAINTIFFS' EXHIBIT P-21457 WAS RECEIVED IN EVIDENCE.)

14 MR. WALLACE: Thank you.

15 Your Honor, as a learned treatise, we'd -- it's my
16 understanding we would not be ultimately providing that to the
17 jury.

18 THE COURT: All right.

19 THE DEPUTY CLERK: It does not go to the jury?

20 THE COURT: That's correct.

21 MR. WALLACE: Correct. But we would like to publish.

22 MR. THOMAS: Yes.

23 MR. WALLACE: Thank you.

24 BY MR. WALLACE:

25 Q. So let's keep moving on, Dr. Guelcher. The article is in

—GUELCHER — DIRECT — WALLACE —

1 front of the jury, at least the first page is. Can you tell
2 us why you found that article significant?

3 A. So, this article was interesting because the authors
4 looked at a hundred explants, a hundred meshes removed from
5 human patients, and tried to understand what was happening in
6 terms of the response these materials had on the body.

7 Q. Could you turn to what would be the fourth page, second
8 column on the right, beginning with the word "analysis"? Do
9 you see that?

10 A. Yes.

11 Q. Okay. Do you recall what sort of analysis was done by
12 the authors that conducted this study?

13 A. Well, they did scanning electron microscopy, or SEM,
14 which is a way for looking at the surface of the material.
15 They did this infrared spectroscopy, which is a way of looking
16 at the chemical groups, chemical bonds on the surface.

17 Q. What does it mean when it says "uneven way"?

18 A. Well, "uneven way" would mean that it's -- it's maybe
19 random, it's associated with manufacturing, not other types of
20 responses.

21 Q. If you could turn to Page 267, please, and look at the
22 area -- the jury has it highlighted in front of them --
23 talking about the chronic inflammatory reaction. Can you tell
24 us --

25 A. Yes.

—GUELCHER - DIRECT - WALLACE—

1 Q. -- whether or not this is at all consistent with your
2 opinions in this case?

3 A. So, this first paragraph explains the chronic
4 inflammatory reaction, in a way that I was explaining as a
5 foreign-body reaction. So this is free radical synthesis as
6 peroxide, superoxide and hypochlorite. These are all reactive
7 oxygen. They're forms of oxygen that are much more reactive
8 than oxygen that's in the air you breathe. So this would be
9 what I was referring to as reactive oxygen species.

10 And then the next sentence says, "Once in contact with
11 the polypropylene implant, these radical species could infer
12 oxidation of the carbon-hydrogen bonds." This is what I was
13 explaining earlier. These radical species or reactive oxygen
14 species that are secreted by inflammatory cells, that oxidize
15 that carbon-hydrogen bond. That is what I was explaining
16 earlier.

17 Q. Do you know -- I'm sorry. Did I interrupt you?

18 A. No. I'm done.

19 Q. Do you know where these 100 explants came from, what part
20 of the body?

21 A. I believe these were pelvic mesh explants, vaginal mesh.

22 Q. Is there anything else that -- in connection with this
23 study, that -- well, let's just move on to the next article.
24 Why don't we do that.

25 The Costello article which is 21468, do we have that?

—GUELCHER — DIRECT — WALLACE—

1 THE COURT: Another learned treatise?

2 MR. WALLACE: Yes, Your Honor.

3 THE COURT: All right.

4 (PLAINTIFFS' EXHIBIT P-21468 WAS RECEIVED IN EVIDENCE.)

5 BY MR. WALLACE:

6 Q. Why did you select this article, Dr. Guelcher?

7 A. Well, this was another article, this is from hernia mesh,
8 but it also explains very clearly how the body can react to
9 implanted polypropylene mesh.

10 Q. What else, if anything, did you find significant about
11 this article?

12 A. Well, this article found evidence of surface cracking,
13 just like we saw in the Ethicon studies. There was surface
14 cracking, there was also surface degradation of the material,
15 by spectroscopy, and there was also a change in the
16 molecular weight of the polypropylene that was explanted from
17 these --

18 THE COURT REPORTER: I'm sorry. The what.

19 THE WITNESS: The molecular weight -- not the
20 molecular weight. I'm sorry. I spoke incorrectly.

21 The melting temperatures changing in these, as well.

22 And so these meshes are showing changes in response
23 to this foreign-body reaction, just like we've seen
24 previously.

25 BY MR. WALLACE:

-GUELCHER - DIRECT - WALLACE -

1 Q. If you look at the second page of the article reporting
2 on this study, beginning with the paragraph that says, "As a
3 result of this chronic inflammatory response" --

4 A. Yes.

5 Q. -- "the mesh material is exposed to a continuous bath of
6 oxidants."

7 A. Yes.

8 Q. Do you see that paragraph?

9 A. Yes.

10 Q. Can you tell the jury the significance of this paragraph
11 to your opinions in this case?

12 A. So this paragraph supports my opinions that this chronic
13 inflammatory response, this is a foreign-body reaction. The
14 mesh material is exposed to a continuous bath of oxidants.

15 Again, these oxidants are reactive oxygen species, more
16 reactive than molecular oxygen, and the mesh is continuously
17 exposed to these materials because the cells are adherent and
18 they secrete these reactive oxygen, and this reaction
19 continues as long as the mesh is there. So these statements
20 are supporting the opinions I --

21 Q. This study talks about both chemical degradation and
22 physical degradation. What is -- what does that mean in
23 connection -- as it relates to your opinions?

24 A. Well, chemical degradation would be these changes in the
25 chemical structure of the polypropylene and this degrading,

—GUELCHER - DIRECT - WALLACE—

1 and, again, these chemical changes can lead to physical
2 changes such as embrittlement and cracking, which is what was
3 observed in this study is these chemical changes lead to
4 physical changes such as cracking in the material.

5 Q. Let's keep moving, Dr. Guelcher. And you mentioned the
6 Wood article.

7 MR. WALLACE: Counsel, that would be 21925. Again,
8 another learned treatise, Your Honor.

9 THE COURT: All right.

10 (PLAINTIFFS' EXHIBIT P-21925 WAS RECEIVED IN EVIDENCE.)

11 BY MR. WALLACE:

12 Q. And, Dr. Guelcher, have you reviewed this study in
13 connection with your work?

14 A. Yes, I have.

15 Q. And do you know when it was published?

16 A. This study was published just last year, 2013.

17 Q. And what is the significance of this study to you in
18 connection with your opinions in this case?

19 A. So, what I found interesting about this study is these
20 were three different types of materials that were removed from
21 the same patient, so it gives us a reference for how three
22 different types of materials respond to the foreign-body
23 reaction in the same patient. So it takes out of
24 consideration the patient-to-patient changes.

25 Q. Do these studies that you've looked at in these three

—GUELCHER - DIRECT - WALLACE—

1 articles confirm your opinion on degradation?

2 A. Yes, they do. Again, this study saw evidence of changes
3 in the polypropylene, cracking, changes in the physical
4 properties of the polypropylene over time.

5 Q. Are these the only three studies that exist in the
6 literature on these issues, Dr. Guelcher?

7 A. No. There are other studies that have shown this as
8 well, that polypropylene responds to this foreign-body
9 reaction and changes, its chemical properties change and its
10 mechanical structural properties change.

11 Q. You talked about the less-mesh concept in the summary of
12 your opinions. I'd like us to move to Slide 17, please.

13 MR. WALLACE: If that's -- before we go there, let's
14 make sure there is no objection.

15 MR. THOMAS: I just have one of the studies
16 referenced on the slide. Are you going to introduce both
17 studies on the slide?

18 MR. WALLACE: We're just going to talk about them. I
19 won't introduce them.

20 MR. THOMAS: I object to the reference to the slide
21 if they're not going to be part of the record in the case.

22 THE COURT: Just ask the question.

23 MR. WALLACE: Fair enough.

24 BY MR. WALLACE:

25 Q. Have you reviewed the Cobb study regarding lightweight

—GUELCHER — DIRECT — WALLACE —

1 mesh in hernia repair?

2 A. Yes, I have.

3 Q. And have you reviewed that in connection with the
4 opinions that you'd offered on the less-mesh concept?

5 A. Yes.

6 Q. Okay. And what, if anything, does the Cobb paper -- or
7 how does the Cobb paper inform your opinions in this case?

8 A. So, the argument in the Cobb paper is that less mesh is
9 better. And this relates back to my opinions in that if the
10 polypropylene is causing the surface reaction and the
11 polypropylene is responding to that foreign-body reaction and
12 changing, the more polypropylene surface that's present, the
13 greater those changes would be, the more hazardous they could
14 be, and so because of this reaction, the polypropylene in
15 response to the body, it's best to minimize the amount of
16 polypropylene that's present in the mesh. This is the
17 argument that Cobb, et al., are making and is consistent with
18 my opinions.

19 Q. Have you reviewed the work of Dr. Klinge and
20 Klosterhalfen in the foreign-body reaction to mesh's paper?

21 A. Yes, I have.

22 Q. And did that --

23 MR. THOMAS: Your Honor --

24 THE COURT: Yes.

25 MR. THOMAS: That's not sufficiently identified.

—GUELCHER - DIRECT - WALLACE—

1 There are dozens, as the Court's well aware, of papers between
2 Klinge and Klosterhalfen on different issues.

3 THE COURT: All right. If you would identify which
4 studies or papers you're talking about.

5 It's time for our afternoon break, I think, if you're
6 going to be going for a little bit longer.

7 MR. WALLACE: Actually, no, Your Honor.

8 THE COURT: Oh, really?

9 MR. WALLACE: I will be done -- if we take a break, I
10 can probably get organized and get done relatively quickly.

11 THE COURT: All right. Ladies and gentlemen, we'll
12 take our afternoon break. I'll call you back in 15 minutes.

13 Don't discuss the case among yourselves. Prevent
14 anyone from discussing it with you or in your presence. I
15 will call you back shortly. Don't use any social media.

16 COURT SERVICES OFFICER: All rise.

17 (The jury left the courtroom at 2:30 p.m.)

18 (The jury entered the courtroom at 2:47 p.m.)

19 THE COURT: You may resume the stand.

20 Mr. Wallace.

21 MR. WALLACE: Thank you. Dr. Guelcher, we're going
22 to proceed.

23 BY MR. WALLACE:

24 Q. I want to go back really briefly just to try to finish up
25 to 21925, and that is the Wood article, and the section on

-GUELCHER - DIRECT - WALLACE -

1 polypropylene on page 1120.

2 A. Yes.

3 Q. And I'm going to ask you to look at the words beginning
4 with "unfortunately". And I'll read it for you, Dr. Guelcher.
5 "Unfortunately, polypropylene will degrade in an oxidizing
6 environment such as the environment during a foreign body
7 response. Because of this, polypropylene has been shown to
8 oxidize in vivo. Oxidization of polypropylene results in
9 surface cracking and cracking, changes in mechanical strength
10 and increased brittleness."

11 Did I read that correctly.

12 A. Yes.

13 Q. And what impact, if any, did this Wood article and what I
14 just read have on your opinions in this case?

15 A. So this Wood article, again, is consistent with my
16 opinion that this oxidizing environment, this is the space
17 between the cell, the cell and the material where we have all
18 this reactive oxygen, that's an oxidizing environment. It
19 says, "such as the environment during the foreign body
20 response." That's the environment I was speaking about. And
21 polypropylene oxidizes in vivo which can cause these changes
22 in chemical composition and also mechanical properties such as
23 brittleness and cracking.

24 Q. Did you address mechanical failure in your report in this
25 case?

—GUELCHER - DIRECT - WALLACE—

1 A. I did. I mentioned that these types of chemical changes
2 can result in mechanical failure of the devices as was
3 observed with the pacemaker lead problem.

4 Q. You gave the jury a few dates about, for example, when
5 foreign body reaction was known and when degradation outside
6 the body was known. Do you know, in connection with reviewing
7 these articles and the work that you've done in the case, when
8 the first study was done to evaluate vaginal mesh implants and
9 the concepts of degradation?

10 A. Well, the Clavé paper that we were discussing earlier,
11 this Clavé paper was published in 2005, so in 2005 they noted
12 that --

13 Q. Let's make sure we're looking at the right document. I'm
14 looking at 21457 which was actually a 2010 publication.

15 A. Yes. Oh, I got the date mixed up. I'm sorry.

16 21457 is this Clavé study, I was looking at the date
17 wrong.

18 Q. And are you looking at the conclusion section?

19 A. I'm looking at the conclusions where they state this is
20 the first study to evaluate synthetic implants used in the
21 vaginal approach.

22 Q. And have you seen any evidence in the work that you've
23 done in this case or any of the work that you've done with
24 respect to polypropylene that Ethicon has done such research?

25 A. I've not seen any research from Ethicon in this area, and

—GUELCHER — DIRECT — WALLACE —

1 again after seeing the degradation of the sutures, as an
2 engineer I would want to know how the Prolene responds to this
3 oxidated environment in the pelvic floor and the mesh, quite
4 different than a suture, but to my knowledge that study has
5 not been done.

6 Q. In connection with your work, did you have to determine
7 whether or not polypropylene was inert?

8 A. Yes, I did.

9 Q. And what did you find?

10 A. Well, based on the testimony that I provided earlier, I
11 do not believe polypropylene is inert. It is oxidatively
12 unstable, it reacts with oxygen, and its chemical composition
13 changes, so I would not call this an inert material because of
14 its reactivity with oxygen.

15 Q. Are there any limitations on the use of polypropylene in
16 the pelvis for a permanent implant as it relates to your
17 opinions in this case?

18 MR. THOMAS: Objection, Your Honor.

19 THE COURT: Let me see you at sidebar.

20 (The following occurred at sidebar.)

21 THE COURT: Mr. Thomas.

22 MR. THOMAS: Yes, Your Honor. That's an opinion that
23 goes directly to the use of mesh in the pelvic floor which is
24 beyond the scope of his expert report.

25 MR. WALLACE: Your Honor, I would just say that I

—GUELCHER - DIRECT - WALLACE—

1 could probably word the question differently and I would go
2 back and just say with respect to his qualifications as a
3 biomedical engineer who's offered his opinions on the case,
4 whether or not as a biomedical engineer there are any
5 limitations with respect to the use of polypropylene inside
6 the pelvis as a biomedical engineer, not a clinical.

7 THE COURT: I'm not sure you still would have
8 established an adequate foundation even if you asked that, but
9 if you want to try to establish a foundation, I'll let you,
10 but that alone I would sustain the objection.

11 MR. WALLACE: Okay. If I could ask, and when you
12 speak of foundation, Your Honor --

13 THE COURT: Well, that is to say as a biomedical
14 engineer, are you familiar with and have you studied chemical
15 composition of the tissues and so forth, and do you have
16 medical training?

17 MR. WALLACE: Okay. And I'll clarify just so with
18 respect to other witnesses, Your Honor, I will be clarifying
19 that he's not a medical doctor, not offering a clinical
20 opinion.

21 THE COURT: Yes. Great. Thank you.

22 MR. WALLACE: Thank you.

23 (Sidebar concluded.)

24 MR. WALLACE: Dr. Guelcher, I have just a few more
25 questions.

—GUELCHER — DIRECT — WALLACE—

1 BY MR. WALLACE:

2 Q. With respect to polypropylene's use inside the body, a
3 very simple question, are you anti-polypropylene when it comes
4 to using polypropylene in other parts of the body?

5 A. No, I'm not opposed to the idea of using polypropylene in
6 the body. One of the important definitions about --

7 MR. THOMAS: Objection, Your Honor. I object to the
8 narrative. He answered the question.

9 THE COURT: I'll sustain it. He gave a direct answer
10 to the question, so I'll sustain it.

11 MR. WALLACE: Yes, Your Honor.

12 If you'll indulge me for one minute, Your Honor.

13 THE COURT: Certainly.

14 MR. WALLACE: I have one more thing.

15 (Discussion was held off the record.)

16 MR. THOMAS: Your Honor, I expect we're going to need
17 to talk about this.

18 THE COURT: All right. Excuse us.

19 (The following occurred at sidebar.)

20 THE COURT: Mr. Thomas.

21 MR. THOMAS: Mr. Wallace advises the next exhibit he
22 wants to use with this witness is an instructions for use and
23 I can't imagine what this witness brings. There's nothing
24 about instructions for use in the opinions that he's disclosed
25 in this case.

—GUELCHER — DIRECT — WALLACE—

1 MR. WALLACE: Do you want me to respond, Your Honor?

2 THE COURT: Sure.

3 MR. WALLACE: I understand that he's not a medical
4 doctor. My question is going to be very simple, whether or
5 not he believes that the statement that polypropylene is not
6 subject to degradation is true or false. He's not offering a
7 clinical opinion. I believe he can say as a matter of fact
8 just what he reviewed and we would still be able to, allowed
9 to offer admission of the IFU and those issues. Would that be
10 acceptable, Your Honor?

11 MR. THOMAS: He's already given his opinion about
12 polypropylene degradation and I think this is inappropriate
13 for this witness.

14 THE COURT: I'll overrule the objection.

15 MR. WALLACE: Your Honor, may I publish the document?

16 THE COURT: You may.

17 (Sidebar concluded.)

18 MR. WALLACE: Your Honor, rather than -- I'm sorry, I
19 might have interrupted.

20 THE COURT: I was going to see if you were going to
21 introduce that.

22 MR. WALLACE: What I would like to do, so that the
23 next witness can talk about it from a clinical perspective,
24 Your Honor, is that I would use one of my opening slides as
25 just a demonstrative with this witness.

—GUELCHER - DIRECT - WALLACE—

1 THE COURT: Why don't I just allow you to ask the
2 question again?

3 MR. WALLACE: Okay.

4 BY MR. WALLACE:

5 Q. Let me ask it this way: If the instructions for use that
6 come with this product, the TVT-O product, say that the
7 product does not degrade, is that a true or false statement?

8 MR. THOMAS: Objection, Your Honor, to the
9 characterization.

10 THE COURT: Overruled.

11 THE WITNESS: So what I've spoken about today is the
12 response of the body -- the response of polypropylene to the
13 foreign body reaction.

14 MR. THOMAS: Objection, Your Honor.

15 THE COURT: Sustained. Non-responsive.

16 BY MR. WALLACE:

17 Q. Can you just answer whether it's true or false?

18 A. I'm trying to give an explanation.

19 THE COURT: You can answer it and then give an
20 explanation.

21 THE WITNESS: Well, last time I tried that I wasn't
22 allowed.

23 THE COURT: Well, consistency is the hobgoblin of
24 small minds.

25 THE WITNESS: That's a good one for a professor, I

—GUELCHER - DIRECT - WALLACE—

1 think.

2 I don't believe that's true. I believe that I
3 pointed to evidence today that shows that polypropylene reacts
4 in response to a reactive oxygen secreted by the foreign body,
5 by inflammatory cells, by inflammatory cells the polypropylene
6 degrades, its chemical composition changes, it becomes
7 brittle, cracks, and undergoes other changes, and this could
8 have negative effects on a patient's health when implanted in
9 the pelvic floor. So I don't believe --

10 THE COURT: The jury will disregard last part of the
11 witness's answer.

12 MR. WALLACE: Thank you, Your Honor.

13 Let's go to the summary of opinions slide so we can
14 finish, Dr. Guelcher.

15 THE COURT: I meant the part about his idea that it
16 could have effect on the patient's health. You're to
17 disregard that and not consider it.

18 I can't answer your questions.

19 THE DEPUTY CLERK: They want to be able to see the
20 slide.

21 THE COURT: Oh, the slide coming up. Sure. You're
22 ahead of me. All right.

23 MR. WALLACE: Thank you, Judge.

24 BY MR. WALLACE:

25 Q. With respect to the opinions that you've offered in your

—GUELCHER — CROSS — THOMAS —

1 report and your testimony today and this summary of opinions,
2 have you held each of these opinions to a reasonable degree of
3 biomedical engineering and chemical engineering certainty?

4 A. Yes, I have.

5 MR. WALLACE: I have no further questions.

6 THE COURT: Thank you, Mr. Wallace.

7 Cross examination.

8 MR. THOMAS: Thank you, Your Honor.

9 CROSS EXAMINATION OF SCOTT GUELCHER, Ph.D., BY MR. THOMAS:

10 Q. Dr. Guelcher, how are you today?

11 A. Good. How are you?

12 Q. Doctor, you testified on direct that polypropylene is a
13 polymer?

14 A. Yes.

15 Q. It was invented in 1950s, correct?

16 A. Yes.

17 Q. And when polypropylene was invented, it was very
18 innovative, wasn't it?

19 A. I mean all materials when they're invented, they're
20 innovative.

21 Q. Plastics, right? The age of plastics and that was a
22 plastic, correct?

23 A. Yes, it is a plastic.

24 Q. Now, Prolene is the brand name for the polypropylene
25 Ethicon uses in its medical devices, correct?

—GUELCHER - CROSS - THOMAS—

1 A. Prolene is a brand name, it's essentially polypropylene
2 with antioxidants and lubricants.

3 Q. And Ethicon first used Prolene in its sutures?

4 A. That's my understanding.

5 Q. And sutures are what we in West Virginia call stitches,
6 right?

7 A. Call them that in Virginia, too, where I grew up.

8 Q. Down in Blacksburg?

9 A. Yes, sir.

10 Q. And so Ethicon Prolene stitches or sutures have been
11 around since the late Sixties?

12 A. That's my understanding, they've been around since the
13 Sixties.

14 Q. And what makes Prolene Prolene as opposed to simple
15 polypropylene are the additives that you talked about,
16 correct?

17 A. Yes. The brand name Prolene is defined by the additives
18 that are added to the polypropylene.

19 Q. And those additives are calcium stearate, do you remember
20 that?

21 A. Calcium stearate is added as a lubricant.

22 Q. And DLTDP because I can't pronounce the full word.

23 A. It's a long word. It's an antioxidant.

24 Q. Santonox R?

25 A. Another antioxidant.

—GUELCHER — CROSS — THOMAS —

1 Q. Procol LA-10?

2 A. I think that's another surfactant.

3 Q. And a CPC --

4 THE COURT: That's another what? I didn't hear it.

5 THE WITNESS: I'm sorry. It's another surfactant or
6 a lubricant.

7 THE COURT: All right.

8 BY MR. THOMAS:

9 Q. And then the coloring, the CPC pigment, correct?

10 A. Yes, sir.

11 Q. And those additives are what make Prolene different from
12 the other polypropylene medical devices on the market,
13 correct?

14 A. There are many different grades of polypropylene; Marlex,
15 Prolene, different grades --

16 THE COURT: Is that a yes or a no?

17 THE WITNESS: I'm sorry. Yes.

18 MR. THOMAS: Thank you.

19 BY MR. THOMAS:

20 Q. Now, Ethicon Prolene sutures are what is known as
21 non-absorbable sutures, correct?

22 A. They're marketed as non-absorbable.

23 Q. Okay. And what that means is they are supposed to be in
24 the body for life?

25 A. They're supposed to be without changing, yes.

—GUELCHER — CROSS — THOMAS —

1 Q. Do you know where Ethicon gets the polypropylene resin
2 used to make Prolene sutures?

3 A. My understanding it comes from Sunoco and is compounded
4 in a plant in Kenova on the Kanawha River.

5 Q. It's made here in West Virginia?

6 A. Yes, it is.

7 Q. And it has been since the beginning of the time they made
8 these sutures, correct?

9 A. My understanding is the plant has changed control, but
10 it's still made in the same plant, it's been bought and sold
11 though.

12 Q. And you know when Ethicon buys this resin from this plant
13 in Kenova, it actually comes down to Kenova and takes over the
14 plant and makes special runs of the Prolene polypropylene at
15 this plant, correct?

16 A. I wouldn't agree that they take over the plant. My
17 understanding is that they work with the personnel in the
18 plant to make sure that Ethicon's concerns are addressed
19 during the campaign.

20 Q. Do you agree that Ethicon personnel thoroughly clean the
21 mixing and compounding equipment before running our Prolene
22 material, Ethicon's Prolene material?

23 A. You're reading that from a document.

24 THE COURT: Would you agree with that or not, or do
25 you know?

—GUELCHER — CROSS — THOMAS —

1 THE WITNESS: I don't know the level of detail that
2 -- I know that they're there and that they're working. This
3 is a common practice, you work with a sole manufacturer to
4 make sure things are done. I'm speaking on my experience.

5 THE COURT: Well, Doctor, the important thing here is
6 just listen to the question and try to answer it as asked. He
7 has asked you a question, whether you know -- would you finish
8 it again there, Mr. Thomas?

9 MR. THOMAS: Your Honor, with the court's permission,
10 I'm going to try to make it a little easier. May I approach
11 the witness?

12 THE COURT: You may.

13 BY MR. THOMAS:

14 Q. Doctor, I'm going to hand you what's been marked as
15 defendant's exhibit 23600. It's a document dated January 23,
16 2003.

17 A. Yes.

18 Q. And it's titled Prolene resin manufacturing
19 specifications.

20 A. Yes.

21 Q. You've seen this document before, haven't you?

22 A. I have seen this document.

23 Q. And this 2003 document discusses the Prolene
24 manufacturing process in Kenova, West Virginia, doesn't it?

25 A. Yes, sir, it does.

—GUELCHER — CROSS — THOMAS —

1 MR. THOMAS: And Jamie, would you give me the first
2 page of that, please, so the jury can see it?

3 THE COURT: Do you want to move its admission?

4 MR. THOMAS: I do, Your Honor. Thank you.

5 THE COURT: Is there objection?

6 MR. WALLACE: No, Your Honor.

7 THE COURT: It may be received and displayed.

8 (DEFENDANTS' EXHIBIT 23600 WAS RECEIVED IN EVIDENCE.)

9 MR. THOMAS: Let's go to the first paragraph, Jamie.

10 BY MR. THOMAS:

11 Q. Do you recall from reading this document, Mr. Guelcher,
12 that back in the Sixties Ethicon went to a company in New York
13 to try to figure out what kind of polypropylene they were
14 going to use in their Prolene sutures, correct?

15 A. That's what it says here.

16 Q. Okay. And they obtained numerous different fiber samples
17 and tested those samples before they chose the one they wanted
18 to use, correct?

19 A. Yes. It doesn't say how, but it says that.

20 Q. Okay. And down in the second paragraph it says that
21 Ethicon personnel could go into the plant to insure that the
22 resin was made under proper conditions of cleanliness,
23 etcetera, and to verify that the formulations were as stated
24 on the run sheets. You knew that, didn't you?

25 A. I'm sorry. What page are you on?

—GUELCHER — CROSS — THOMAS —

1 Q. On the front page in the second paragraph, right in the
2 middle.

3 A. Okay. Mine is organized a little differently. I see.
4 Various deals were struck, Ethicon could go into the plant.
5 That's what I was saying earlier, yes.

6 Q. Okay. And they bought multi-year supplies at one time,
7 do you remember that from reading the document?

8 A. What I understand is they would do a campaign every
9 couple years, they would make a lot of material.

10 Q. So the current practice, end of that paragraph, of week
11 to two week long campaigns every two years, that's how they
12 made their Prolene, correct?

13 A. That's what it says.

14 Q. And so you go down to the bottom of the third paragraph.
15 From the beginning of the Sixties, Ethicon has always bought
16 its Prolene from the same plant using the same equipment, with
17 the exception of the polymer reactor, and made by the same
18 people, except for those who have been retired or replaced,
19 correct?

20 A. That's what it says, yeah.

21 Q. Now, the second page of that document lists the additives
22 that are in Prolene that we talked about a minute ago,
23 correct?

24 A. Yes, sir.

25 Q. And the next paragraph tells about the manufacturing

—GUELCHER — CROSS — THOMAS —

1 process for Prolene. And Ethicon insists that the mixing and
2 compounding equipment be thoroughly cleaned prior to running
3 our material. Do you see that? Right under the additives.

4 A. Under the additives. Yes. I see it.

5 Q. And Aristech, the owner, and Ethicon inspect the
6 equipment before commencing operations; do you see that?

7 A. That's what it says.

8 Q. And once they start the compounding campaign, the first
9 500 to a thousand pounds that are compounded are discarded as
10 a matter of course; do you see that?

11 A. That's a fairly common practice, yeah, I understand.

12 Q. And if the molecular weight of the natural, paren,
13 unpigmented material is acceptable as measured by melt float,
14 we then start collecting material. You know the importance of
15 molecular weight here, don't you?

16 A. I do, but I don't know what's acceptable means, the
17 specification.

18 Q. What's the importance of an appropriate molecular weight
19 for polypropylene?

20 A. Well, the molecular weight has an effect on the
21 properties, but again, it should be within some specification.
22 I don't know what's acceptable --

23 Q. I didn't ask you that question. I'm asking you about
24 molecular weight. And so it's important to have an
25 appropriate molecular weight for the product before it's

—GUELCHER — CROSS — THOMAS —

1 released, you'd agree with that?

2 A. Molecular weight is typically something we put a
3 specification on.

4 Q. Okay. And you know this process hasn't changed over the
5 last 50 years?

6 A. That's what this document says.

7 Q. Do you have any reason to disagree with that?

8 A. There were some changes to the formulation, I understand,
9 the antioxidants were changed in the early 1990s. That was
10 changed. The plant actually changed owners I think a number
11 of times.

12 Q. But the equipment's the same?

13 A. The facility and the equipment seem to be the same.

14 Q. Do you have any idea of the uses of polypropylene Prolene
15 sutures in the human body?

16 A. I know that they're used as sutures for a number of
17 applications.

18 Q. Do you know whether they come in different sizes?

19 A. I know that they come in different sizes.

20 Q. Why do they come in different sizes?

21 A. Well, I'm not a clinician, but I would assume you'd want
22 different sizes for different types of surgeries that are
23 being done.

24 Q. Do you know how many Prolene sutures have been implanted
25 in people around the world since the Sixties?

—GUELCHER — CROSS — THOMAS —

1 A. That's not a statistic that I'm aware of.

2 Q. Billions, with a B?

3 A. Okay.

4 Q. Do you have any idea whether to disagree with that or
5 not?

6 A. I said I don't know what the number is. It sounds like
7 it's --

8 Q. A bunch?

9 A. It's a lot of hamburgers, yeah.

10 Q. That's a legal term. I'm sorry. I apologize.

11 You know from your review of your documents in this
12 case that Ethicon began using Prolene polypropylene in hernia
13 mesh in the mid 1970s, correct?

14 A. Yes, that's my understanding.

15 Q. And the, I think you testified that the mesh used in
16 hernia mesh is a bigger piece of mesh, but exactly the same
17 design as that used in TVT, correct?

18 A. I don't think I said that. I don't think I was comparing
19 hernia to --

20 Q. Let me ask it this way: Do you know how the Ethicon
21 Prolene hernia mesh compares to the Ethicon Prolene mesh used
22 in TVT?

23 A. My understanding is that similar mesh is just used in
24 similar products but cut to different shapes, that's my
25 general understanding.

—GUELCHER — CROSS — THOMAS —

1 Q. Do you know whether the hernia mesh comes in bigger
2 sheets than the mesh that's in the TVT?

3 A. I would presume that it would since it's used for a
4 different use than a sling.

5 Q. And the Prolene used in the hernia mesh is the same
6 chemical composition as the Prolene used in the sutures,
7 correct?

8 A. It's the same composition, but that doesn't mean it's
9 going to respond the same.

10 Q. I understand. I just asked you the composition.

11 A. The composition is the same.

12 Q. Okay. Do you know how many millions of Prolene
13 polypropylene hernia meshes have been implanted in people
14 around the world since 1975?

15 A. I assume it's millions and not billions from what you --
16 THE COURT: I couldn't hear you.

17 THE WITNESS: I said it sounds like it's millions and
18 not billions. I don't know the number.

19 BY MR. THOMAS:

20 Q. Okay. Now, you're aware from your work in this case that
21 Ethicon polypropylene mesh began being used for the treatment
22 of stress urinary incontinence in a TVT mesh in 1996; you know
23 that, don't you?

24 A. That's correct. To my knowledge.

25 Q. And the Prolene mesh used for the treatment of stress

—GUELCHER — CROSS — THOMAS —

1 urinary incontinence in the TVT mesh is the same chemical
2 composition as the Prolene polypropylene mesh in the hernia
3 mesh, correct?

4 A. It's all sold as Prolene mesh, so I would assume it has
5 the same composition.

6 Q. Do you know?

7 A. It's called Prolene, it's Prolene --

8 THE COURT: Do you know?

9 THE WITNESS: Yes. It's the same.

10 BY MR. THOMAS:

11 Q. So the Ethicon TVT mesh used for the treatment of stress
12 urinary incontinence is also the same chemical composition as
13 the Prolene suture, correct?

14 A. It's the same chemical composition.

15 Q. Do you know how many people have received, around the
16 world, the Prolene mesh for the treatment of stress urinary
17 incontinence?

18 A. I don't know the exact number. I think it's in the
19 thousands.

20 Q. Okay. Now, prior to getting involved in litigation of
21 these cases, you had not seen in any of your research that
22 there was a problem with polypropylene mesh, true?

23 A. I'm not studying in my research, research standard on
24 polypropylene mesh --

25 Q. Is that true?

—GUELCHER — CROSS — THOMAS —

1 A. I think it's true. I'm not aware of any.

2 Q. Now, prior to your work on these cases, you had never
3 done research on polypropylene as an implantable biomaterial,
4 true?

5 A. Not researched polypropylene as an implantable
6 biomaterial, but I've --

7 THE COURT: True or not true?

8 THE WITNESS: I've not done research on it as an
9 implantable biomaterial.

10 THE COURT: True or not true?

11 THE WITNESS: True.

12 BY MR. THOMAS:

13 Q. Prior to getting involved in litigation of these cases,
14 you had never published an article on the use of polypropylene
15 in mesh, true?

16 A. That's true.

17 Q. And prior to getting involved in this litigation, you had
18 never published any article on polypropylene specifically,
19 true?

20 A. That's true.

21 Q. And prior to getting involved in this litigation, you had
22 never given a presentation to any of your colleagues on
23 polypropylene, true?

24 A. That's true, but I am this fall.

25 Q. Thank you. And indeed, prior to getting involved in this

—GUELCHER — CROSS — THOMAS —

1 litigation, you had not even studied polypropylene, true?

2 A. No, that's not true. And I know you're going to pull out
3 my deposition on this, but --

4 MR. THOMAS: Excuse me, Your Honor.

5 THE COURT: Just wait. Just wait. Not a question
6 pending right now.

7 THE WITNESS: Yes, sir.

8 MR. THOMAS: May I approach the witness, Your Honor?

9 THE COURT: You may.

10 BY MR. THOMAS:

11 Q. Now, Dr. Guelcher, you've given depositions in this
12 litigation before, correct?

13 A. Yes, I have.

14 Q. And the way depositions work, for the jury, maybe they
15 don't know what a deposition is, you meet with a lawyer in the
16 room and you swear to tell the truth and you answer questions
17 about the litigation before you come in here to testify,
18 correct?

19 A. That's right.

20 Q. And when you're asked questions you give truthful
21 answers?

22 A. I give truthful answers, but sometimes the context of the
23 question can change from the deposition to a trial.

24 Q. If you'll look at your March 25, 2014 deposition on page
25 79, line three, and the question is asked -- do you have that?

—GUELCHER — CROSS — THOMAS —

1 A. I do.

2 Q. Okay. And the question is asked at line three, "And
3 you've not studied polypropylene before your work in this
4 case, correct?"

5 "No. But I've studied oxidating degradation of other
6 polymers?"

7 Did I read that correctly?

8 A. You read it correctly, but I think the word studied is
9 vague.

10 Q. Thank you.

11 A. He's trying to impeach my testimony. Can I give an
12 explanation? I have one.

13 THE COURT: Stop. Now. I'm not going to put up with
14 quarrelling from either side. The answer is "no". You've
15 asked me if you may explain your "no" answer. The answer to
16 that is "yes".

17 THE WITNESS: Thank you, sir. I appreciate it.

18 THE COURT: Go ahead.

19 THE WITNESS: I'm sorry for the court.

20 THE COURT: That's all right. I'm just doing what I
21 do.

22 THE WITNESS: I understand.

23 I think the word studied in different contexts can
24 mean different things. I had not done research on
25 polypropylene prior to this litigation. I'm not hiding

—GUELCHER — CROSS — THOMAS —

1 anything. But I have taught a course, developed a course on
2 polymer science and engineering at Vanderbilt, I taught it for
3 two semesters, other professors teach it now, and we talked
4 about many types of polymers in this course. So I am familiar
5 with polypropylene, but I do agree that I've not studied it in
6 my research. So it's just this word that I am struggling a
7 little bit with. If you asked me if I've done research, I
8 would say no, I have not, but I have studied and I am aware of
9 the material.

10 THE COURT: All right. Next question.

11 MR. THOMAS: Thank you, Your Honor.

12 BY MR. THOMAS:

13 Q. Now, you obviously know that Ethicon's TVT mesh is
14 designed to be implanted in the human body?

15 A. Yes, that's correct.

16 Q. And you know when those meshes are removed from the human
17 body then they're called an explant?

18 A. That's what I was explaining earlier.

19 Q. You have never analyzed a TVT mesh explant manufactured
20 by Ethicon for the treatment of stress urinary incontinence,
21 true?

22 A. I've not had any explant to --

23 Q. True?

24 A. -- characterize, so --

25 Q. I'm sorry. I don't mean to stop you, but --

—GUELCHER — CROSS — THOMAS —

1 THE COURT: I'll take that as an objection as
2 non-responsive. I'll sustain the objection and direct the
3 witness to answer the question as asked.

4 THE WITNESS: That's true, I've not tested it.

5 THE COURT: Can I see counsel at sidebar?

6 (The following occurred at sidebar.)

7 THE COURT: We're coming close or at least it seems
8 to me to discussing the other mesh cases. I want just to be
9 very sure we don't do that.

10 MR. THOMAS: I'm trying to tailor my questions to
11 Ethicon specifically, Your Honor.

12 MR. WALLACE: Just fair warning, he has looked at
13 mesh and you're about to open a can of worms.

14 THE COURT: He was specific that it was only Ethicon
15 and I'm worried about the witness --

16 MR. WALLACE: I'm not sure he completely gets where
17 he's going.

18 THE COURT: Are you going to ask more questions about
19 that, explant testimony?

20 MR. THOMAS: Just Ethicon specific.

21 THE COURT: Make it clear that you only want an
22 answer about Ethicon.

23 MR. THOMAS: Yes, sir.

24 THE COURT: Just this particular case.

25 (Sidebar concluded.)

—GUELCHER — CROSS — THOMAS —

1 THE COURT: I apologize to Mr. Wallace and Mr.
2 Thomas, to you, Doctor. Proceed.

3 BY MR. THOMAS:

4 Q. In fact, Dr. Guelcher, you've never requested to analyze
5 a mesh manufactured by Ethicon for the treatment of stress
6 urinary incontinence, true?

7 A. Not directly. The company I work for has, I believe.

8 Q. Do you have your deposition in front of you again?

9 A. Yes.

10 Q. Turn to page 21, please, of your March 25 deposition.

11 Are you there?

12 A. Yes.

13 Q. "Question: Have you ever requested to analyze a mesh
14 manufactured by Ethicon for the treatment of stress urinary
15 incontinence?"

16 "Answer: Not to my knowledge."

17 A. Yes.

18 Q. Thank you.

19 A. That's what I said.

20 Q. I need a little help from --

21 MR. WALLACE: Your Honor -- go ahead.

22 Your Honor, there was no impeachment there. I'd just
23 move to just strike the entire questioning from the
24 deposition. It wasn't the question that was asked.

25 THE COURT: Well, everybody's doing, ladies and

—GUELCHER — CROSS — THOMAS —

1 gentlemen, everybody is doing their job as best they see fit.
2 I'll help out a little bit.

3 If you just answer the question and leave it to the
4 lawyer who called you, if he thinks that something needs
5 further explanation, he'll get back up on redirect and get
6 back into it.

7 THE WITNESS: I understand.

8 THE COURT: All right.

9 MR. WALLACE: Thank you.

10 THE COURT: You're welcome.

11 MR. THOMAS: I need some help with the plaintiff's
12 Power Point presentation. Can we go to page seven of the
13 plaintiff's Power Point presentation, please?

14 BY MR. THOMAS:

15 Q. Dr. Guelcher, on the direct examination you were talking
16 about, the title is *Oxidation Alters the Structure of*
17 *Polypropylene*, and what you're explaining there is the
18 chemical reaction between oxygen and polypropylene, correct?

19 A. That's right.

20 Q. And when you have oxidation impacting polypropylene, you
21 have a change in molecular structure, don't you?

22 A. That's right.

23 Q. And you have a change in molecular weight, don't you?

24 A. That's right. It happens at the surface layer.

25 Q. You have a change in molecular weight, didn't you?

—GUELCHER — CROSS — THOMAS —

1 A. Yes.

2 Q. And one of the ways that you measure the extent to which
3 a chemical -- strike that.

4 One of the ways that you measure the extent to which a
5 substance degrades or oxidizes is by a change in molecular
6 weight, true?

7 A. That's one way of measuring it, yes.

8 Q. Okay. And this oxidation that you've described in this
9 chemical structure is also intended to show that the
10 mechanical properties of the product can also change, correct?

11 A. Well, what's being shown here is just the chemical
12 reaction. I'm not sure what you mean.

13 Q. But the progression of that is, as you've testified on
14 direct examination, that you ultimately have a change in the
15 physical properties of that substance, correct?

16 A. Yes.

17 Q. Like tensile strength, correct?

18 A. That's true, yes.

19 Q. Or toughness, correct?

20 A. Yes.

21 Q. And so that you can actually measure, by analytical
22 chemistry and benchtop testing, the extent to which a
23 substance has undergone degradation as you've described it in
24 this slide, correct?

25 A. That's right. That's one way of measuring it.

—GUELCHER — CROSS — THOMAS —

1 Q. Now, if you go to the next slide in this set, you're
2 talking about the implant materials selection. This
3 polypropylene, does the polypropylene in this slide, is this
4 Prolene?

5 A. No, this isn't Prolene; this is polypropylene.

6 Q. Okay. And we talked about before that Prolene without
7 antioxidants?

8 A. That's not Prolene.

9 Q. Exactly.

10 A. It's polypropylene.

11 Q. And as you add antioxidants to it, you do so to stabilize
12 the polypropylene, correct?

13 A. To get the oxidation, yes.

14 Q. And the reason why you do that is to extend the life of
15 the polypropylene for whatever it's being used for, correct?

16 A. That's right, yes.

17 MR. THOMAS: May I approach, Your Honor?

18 THE COURT: You may.

19 BY MR. THOMAS:

20 Q. Now, Dr. Guelcher, I've handed you what's been marked as
21 defendants' exhibit 30884 and this is a 1976 study called
22 *Subcutaneous Implants of Polypropylene Filaments*, first author
23 Liebert, correct?

24 A. Yes.

25 Q. And you're familiar with this paper, aren't you?

—GUELCHER — CROSS — THOMAS —

1 A. I cited this paper in my report.

2 Q. And in the Liebert paper, the authors there tested
3 polypropylene without antioxidants against polypropylene with
4 antioxidants, correct?

5 A. They did, but they were different components, but they
6 did, yes.

7 Q. Thank you.

8 And if you go to page two of this exhibit, 3884.2, down
9 at the bottom it says, "The objectives of the study were
10 determined the length of time required for observable
11 degradation to occur, the type of degradation products formed,
12 the rate of degradation, and four, the effect of the presence
13 of an antioxidant on degradation and the rate of degradation."

14 Do you see that?

15 A. That's right. That's what it says.

16 Q. And what the Liebert article found was that there was no
17 oxidation of the polypropylene treated with antioxidants,
18 correct?

19 A. At 90 days they found that.

20 Q. Correct?

21 A. At 90 days, yes.

22 Q. And at paragraph five on the last page under conclusions,
23 the Liebert group concludes, "Infrared spectra and mechanical
24 testing of implanted and non-implanted filaments containing an
25 antioxidant show no changes in chemical or physical properties

—GUELCHER — CROSS — THOMAS —

1 as a result of implantation." Correct?

2 A. I would agree with that statement up to 90 days.

3 Q. Thank you.

4 THE COURT: I'm sorry. You can't agree or disagree?

5 You have a partial agreement, is that right?

6 THE WITNESS: I have a partial -- I don't know how
7 much -- I don't want to step out of line again. I don't know
8 how much I can say.

9 THE COURT: All right. Okay.

10 THE WITNESS: Partial agreement is fair.

11 BY MR. THOMAS:

12 Q. Now, you are of the opinion that there is no antioxidant
13 package available that can effectively stabilize polypropylene
14 against the threat of oxidation, correct?

15 A. I believe that I said the antioxidants are depleted in
16 time, so that they don't last forever. I believe that's what
17 I said.

18 Q. Do you agree with the statement that I made?

19 A. Could you read it again?

20 Q. You are of the opinion that there is no antioxidant
21 package available that can effectively stabilize polypropylene
22 against the threat of oxidation.

23 A. I don't know of any. I guess I would agree. I don't
24 know of any that would.

25 Q. And you know what a peer-reviewed study is, don't you?

—GUELCHER — CROSS — THOMAS —

1 A. Yes, I've published a lot of peer-reviewed studies.

2 Q. And a peer-reviewed study is one that somebody writes and
3 subjects to review by your peers before it's published,
4 correct?

5 A. That's how it works.

6 Q. And in the 50 years that Prolene polypropylene has been
7 used for implantation in humans, you're not aware of any
8 peer-reviewed study which suggests that Ethicon Prolene loses
9 its antioxidant package such that it oxidizes and becomes
10 embrittled, are you?

11 A. I've not seen that in a peer-reviewed study.

12 Q. You don't have an opinion in this case about whether Mrs.
13 Huskey's mesh degraded, do you?

14 A. I believe it degraded based on the foreign body reaction,
15 but I don't have the data, is that fair?

16 Q. You don't know whether the mesh is brittle, do you?

17 A. I've not tested it.

18 Q. You don't know whether it's oxidized at all, do you?

19 A. As I said, I believe it is, but I've not tested it
20 because I don't have it.

21 Q. That's because you don't have the material to test,
22 correct?

23 A. Yes, sir, that's right.

24 Q. Let's go to page 10 of the Power Point presentation,
25 please.

—GUELCHER — CROSS — THOMAS —

1 Now, you talked to the jury at some length about this
2 flow chart, the effect of the foreign body reaction on
3 implants, and just so it's clear, what you depict here is not
4 your experience with polypropylene, correct?

5 A. What I show here is based on the experience with the
6 pacemaker lead insulation and what I believe is happening to
7 polypropylene.

8 MR. THOMAS: Your Honor, move to strike. Ask him to
9 answer the question.

10 THE COURT: Sustained. The witness is directed to
11 answer the question.

12 THE WITNESS: Okay. Sorry. What's the question
13 again?

14 BY MR. THOMAS:

15 Q. Dr. Guelcher, what you showed here is not related to your
16 experience with polypropylene?

17 A. Not my experience.

18 Q. What you show here is your experience with polyether
19 urethane, correct?

20 A. It's not my experience. It's published experience, yes.

21 Q. You've not done this analysis, testing it, analyzing it,
22 published it, with respect to polypropylene, have you?

23 A. No. But I'm in the process of doing that. I'm sorry.

24 MR. THOMAS: Your Honor, move to strike.

25 THE COURT: Sustained.

—GUELCHER — CROSS — THOMAS —

1 THE WITNESS: I have not done it yet.

2 BY MR. THOMAS:

3 Q. Now, you talked about the seven-year dog study. There
4 was no evidence of embrittlement in the sutures tested in the
5 seven-year dog study, do you agree with that?

6 A. Yes, there was no embrittlement reported in that study.

7 Q. Thank you.

8 A. Well, can I qualify it?

9 Q. And there was no evidence of mechanical breakage in the
10 seven-year dog study, correct?

11 A. I believe on the surface there was evidence of
12 embrittlement, but what you've asked me --

13 Q. There's no evidence of mechanical breakage in the
14 seven-year dog study?

15 A. I do agree that there's no evidence of mechanical
16 breakage.

17 Q. And no evidence of loss of the mechanical properties of
18 the sutures in the seven-year dog study, do you agree with
19 that?

20 A. Can I be specific? There was tensile strength,
21 elongation and modulus, and those parameters were not changed.
22 Well, they were changing, but --

23 THE COURT: Can you answer the question?

24 A. Those three prongs.

25 Q. Thank you.

—GUELCHER — CROSS — THOMAS —

1 MR. THOMAS: May I approach, Your Honor?

2 THE COURT: You may.

3 BY MR. THOMAS:

4 Q. Dr. Guelcher, I'm handing you what's been marked as
5 defendants' exhibit 23228.

6 A. Yes.

7 Q. And 23228 is entitled, *Seven-Year Dog Study*.

8 A. Yes, I've seen this.

9 Q. It's a bigger version of what you talked about on direct?

10 A. Yes, sir.

11 Q. Has more information than what we talked about on your
12 direct examination, do you realize that?

13 A. Yes. I've seen the entire study.

14 Q. And the last three pages of that study are the mechanical
15 properties testing conducted on the mesh after seven years,
16 correct?

17 A. Yes.

18 Q. And it's this testing after seven years that showed that
19 the mesh explanted from the dogs after seven years did not
20 lose any of its physical properties, correct?

21 A. I would not say it does not lose any of its physical
22 properties. They measured strength, elongation and modulus.

23 Q. For what they tested they didn't lose any of their
24 physical properties, correct?

25 A. For what they tested.

—GUELCHER — CROSS — THOMAS —

1 Q. Is that true?

2 A. Yes.

3 Q. Thank you.

4 And also, if you go to page 115 -- are you at 115?

5 A. I'm at 115.

6 Q. Okay. Turn the page briefly. 116 is the area where you
7 testified to the jury about the conclusions, correct?

8 A. That's right.

9 Q. And it's conclusions under optical microscopy and
10 scanning electron microscopy, correct?

11 A. Right.

12 Q. And those would be visual observations of the test,
13 correct?

14 A. Well, it's scanning -- it's high magnification, it's
15 visual.

16 Q. It is visual, correct?

17 A. It is visual of the surface, yes.

18 Q. Well, Ethicon also conducted some analytical chemistry on
19 the mesh they explanted from the dogs too, didn't they?

20 A. They did.

21 Q. And if you go to page 115, they talk about GPC testing,
22 correct?

23 A. Yes.

24 Q. GPC testing is gel permeation chromatography, correct?

25 A. That's what it stands for.

—GUELCHER — CROSS — THOMAS —

1 Q. And gel permeation chromatography measures molecular
2 weight, right?

3 A. That's right, measures molecular weight.

4 Q. And what the company found when it measured the molecular
5 weight after of these sutures after 17 years is that there was
6 no significant difference in molecular weight, correct?

7 A. A couples things. Not 17 years, seven years.

8 Q. I misspoke. Let me ask the question again so it's clear.
9 Isn't it true that the company reported on October 15, 1992
10 that the results of the gel permeation chromatography test run
11 on Prolene sutures explanted from dogs after seven years
12 showed no significant difference in molecular weight, correct?

13 A. That's the way they explain it, but there's not much
14 difference that's given there.

15 Q. Thank you.

16 Do you have the Wood article in front of you?

17 A. Yes, sir, I've got it right here.

18 Q. Wood?

19 A. Wood.

20 Q. The Wood article addressed hernia meshes, correct?

21 A. Yes, sir.

22 Q. It doesn't address Prolene polypropylene, does it?

23 A. It doesn't say Prolene, it says polypropylene.

24 Q. Okay. The Costello article.

25 A. Yes.

—GUELCHER — CROSS — THOMAS —

1 Q. I'm sorry, I don't have the number in front of me. Do
2 you have the number?

3 A. Yes. It's 21468.

4 Q. The Costello article to which you referred on direct, if
5 you go to page two, that's a different mesh company
6 altogether, isn't it? It's a Bard mesh, see under materials
7 and methods?

8 A. It's a Bard mesh with a polypropylene component.

9 Q. Okay. But it's not Prolene polypropylene, is it?

10 A. It's not Prolene.

11 Q. Now, let's go to the Clavé article. Would you bring that
12 up, please? It's 21457.

13 If you go to the sixth page of that, under discussion?

14 A. Yes.

15 Q. Just the first paragraph under discussion, please.

16 A. I'm looking for it.

17 Q. It says, "The primary objectives of this study were to
18 objectively observe a series of prosthetic explants and to
19 characterize potential degradation which may occur in vivo."
20 Correct?

21 A. That's what it says.

22 Q. Those are the goals. And they did it by a number of
23 analytical chemistry tests, correct?

24 A. Yes.

25 Q. And if you go to the bottom right-hand corner of that

—GUELCHER — CROSS — THOMAS —

1 same page, under several hypotheses, last paragraph? Can we
2 blow that up for the jury, please?

3 "Several hypotheses concerning the degradation of the
4 polypropylene are described below. None of these,
5 particularly direct oxidation, could be confirmed in this
6 study."

7 Did I read that correctly?

8 A. You read that correctly. That's the author's opinion.

9 Q. They're the ones that did the study, correct?

10 A. That doesn't mean I agree with that statement.

11 Q. Well, you've not done this study, have you?

12 A. No, but it's common to see papers --

13 Q. Okay. Thank you.

14 THE COURT: I cautioned you about argument. Let's
15 just stop arguing.

16 THE WITNESS: Okay. Sorry.

17 BY MR. THOMAS:

18 Q. Next page, please.

19 Under direct oxidation of the polypropylene, last
20 sentence.

21 A. Yes.

22 Q. FTIR is an analytical chemistry technique where you
23 determine the extent to which there's oxidation in
24 polypropylene, correct?

25 A. I spoke about that in my direct, yes.

—GUELCHER — CROSS — THOMAS —

1 Q. And what you didn't speak about on direct is the last
2 line of that paragraph that says, "The FTIR analysis neither
3 confirmed nor excluded oxidation of polypropylene in the in
4 vivo environment." Correct?

5 A. Again, I don't share that opinion, but that's what they
6 wrote.

7 Q. That's what the people who did the testing said, correct?

8 A. I don't want to argue.

9 Q. Go to the next page, number eight. And on the right side
10 they're doing DSC analysis, correct?

11 A. Yes.

12 Q. And DSC analysis is like a melting point type of analysis
13 so you can determine whether the melting point of a substance
14 changed to determine whether the chemical composition changes,
15 correct?

16 A. So DSC measures transitions in melting temperature and
17 heat of fusion.

18 Q. Okay. And you look under in this study, do you see this?
19 "In this study, no difference between DSC thermograms of
20 pristine and degraded samples was found. Additionally FTIR
21 analysis did not conclusively confirm that the degradation was
22 due to oxidation."

23 Did I read that correctly?

24 A. The FTIR -- yes, you read it correctly. The FTIR refers
25 to the previous comment.

—GUELCHER - REDIRECT - WALLACE—

1 MR. THOMAS: Your Honor, may I have a moment?

2 THE COURT: You may.

3 MR. THOMAS: That's all the questions I have, Your
4 Honor.

5 THE COURT: Redirect.

6 MR. WALLACE: Your Honor, may I proceed?

7 THE COURT: You may.

8 REDIRECT EXAMINATION OF SCOTT GUELCHER BY MR. WALLACE:

9 Q. You were asked some questions by Mr. Thomas about the
10 Costello article and the Wood article, and asked whether or
11 not the polypropylene in those articles were Prolene. Do you
12 remember that?

13 A. Yes, sir.

14 Q. But you weren't asked by Mr. Thomas about the Clavé
15 article and whether or not there was Prolene in that article.

16 A. Yes.

17 Q. Were you?

18 A. No, I was not.

19 Q. Can we pull up the images on page 265?

20 LDPMMF, the one on the right.

21 A. Yes.

22 Q. Do you see that?

23 A. This is not Clavé.

24 Q. Yes, that's Wood. We'd like to put up Clavé. Let me
25 give you the number. That is 21457.

GUELCHER - REDIRECT - WALLACE

1 Dr. Guelcher, just to refresh your recollection, you
2 weren't asked about whether or not this article, the Clavé
3 article, which has a hundred explanted vaginal mesh devices,
4 had any of the polypropylene as Prolene, were you?

5 A. I was not asked that question.

6 Q. And isn't it true that in this article Prolene was
7 examined and degradation was found?

8 THE COURT: Sustained. It is leading. I know it's
9 tempting.

10 MR. WALLACE: Very tempting, Your Honor.

11 BY MR. WALLACE:

12 Q. In examining the Clavé article, did you find that Prolene
13 was a polypropylene mesh that was examined in this study?

14 A. So on this same page it says the DSC thermograms of
15 treated degraded and non-degraded LDPPMF explants were similar
16 to those of treated Prolene soft. Additionally, the DSC
17 thermograms of degraded --

18 THE COURT: Could you slow down a bit?

19 THE WITNESS: I can. Being a professor is hard, you
20 talk too fast.

21 The DSC thermograms of degraded and non-degraded
22 HDPPMF explant were also similar to those of treated pristine
23 Prolene samples.

24 Q. Thank you. Let's move on in the article, Doctor. Let's
25 move to page 270 and you'll probably see in your copy there is

GUELCHER - REDIRECT - WALLACE -

1 some things at the top of the page.

2 A. Yes.

3 Q. I'm going to refer you to the left-hand column beginning
4 with the word polypropylene that's already highlighted. If
5 you could highlight down to the bottom of the column there.

6 A. Yes.

7 Q. And I ask if you could read that first paragraph, please,
8 and tell me whether or not Mr. Thomas asked you about that
9 paragraph.

10 A. "Polypropylene, in particular, LDPPMF, is the most used
11 material in the PFD surgery. It is generally considered an
12 inert material. This study contradicts this established fact
13 and confirms the results of other studies on polypropylene
14 materials used in other areas of medical specialization."

15 I was not asked about this paragraph.

16 Q. And with respect to the LDPPMF, is that what was referred
17 to as the Prolene?

18 A. From the previous page that I read, yes.

19 Q. Thank you.

20 And you were asked now -- well, you were asked about
21 Clavé, Wood and Costello. Did each of those studies confirm
22 degradation?

23 MR. THOMAS: Objection, Your Honor. Asked and
24 answered. Beyond the scope.

25 THE COURT: I'm going to allow it. And it's leading.

GUELCHER - REDIRECT - WALLACE -

1 But I want to get.

2 THE WITNESS: In my direct examination I testified
3 that those papers point to degradation either through surface
4 cracking, changes in other types of properties. In my opinion
5 they all point to degradation.

6 BY MR. WALLACE:

7 Q. Did Mr. Thomas present you with one study that says --

8 THE COURT: Let's don't do argumentative stuff.

9 MR. WALLACE: I'm sorry, Your Honor.

10 Q. Did Mr. Thomas present you with any studies that say
11 pelvic floor mesh does not degrade?

12 A. He did not present me with any studies and I've not seen
13 any studies that state that.

14 Q. You were asked some questions about embrittlement on
15 cross examination. In your review of Ethicon documents, did
16 you see whether or not Ethicon did any research on its meshes
17 whatsoever for embrittlement?

18 A. I've not seen the studies in the meshes. The sutures
19 studies did point to embrittlement on the surface. And it
20 starts at the surface --

21 MR. THOMAS: Your Honor, object. It's
22 non-responsive.

23 THE COURT: First part of the answer is directly to
24 the question and may be considered by you. When the doctor
25 started going on, you're to ignore that.

GUELCHER - REDIRECT - WALLACE -

1 THE WITNESS: My students do that, too.

2 BY MR. WALLACE:

3 Q. As a biomedical engineer that's offered opinions in this
4 case and the evidence you've reviewed and your experience
5 working on polypropylene mesh, do you think it's important for
6 a medical device manufacturer to test for embrittlement before
7 putting polypropylene mesh into women?

8 MR. THOMAS: Objection, Your Honor. Beyond the
9 scope.

10 THE COURT: I sustain it as beyond the scope.

11 BY MR. WALLACE:

12 Q. You were asked some questions about a plant at the
13 beginning of your cross examination. Do you recall that line
14 of questioning?

15 A. Yes, I do.

16 Q. Whether or not there's a clean plant, does that affect
17 your opinions in this case?

18 A. No. It just tells me that there's a reproducible way to
19 manufacture the material, that it's not changed.

20 Q. Does clean polypropylene degrade?

21 A. All polypropylene degrades.

22 Q. Have you -- you were asked some questions about your
23 experience with vaginal mesh. Have you given any scientific
24 presentations on vaginal mesh failures at any scientific
25 conferences?

—GUELCHER - REDIRECT - WALLACE—

1 MR. THOMAS: Your Honor, I'm --

2 THE COURT: Can I see counsel?

3 (The following occurred at sidebar.)

4 THE COURT: Let me just shortcut this. I don't
5 recall him being asked about his experience with vaginal mesh.

6 MR. WALLACE: Sure. He was asked about his
7 experience with researching polypropylene and the work done in
8 this case. All I was simply pointing out is that he's been
9 asked to present at conferences regarding his research. So if
10 I phrase the question differently, I could do that and just
11 move on.

12 THE COURT: I don't quite know what you're doing.

13 MR. THOMAS: Your Honor, that's really getting into
14 the area that we're trying to avoid because if he has any
15 research at all, it's not in this case, it's in the other
16 cases. And if I'm going to cross examine him at all -- and
17 just for court's benefit, I know for a fact that he and his
18 co-expert, Dr. Dunn, have conducted extensive analytical
19 testing on other meshes. I could have gone into that at great
20 length because he didn't do the same kind of testing here, and
21 it's the same kind of issue. That's the kind of research that
22 he's doing that they're presenting at these conferences and I
23 just don't want to get into this.

24 THE COURT: Okay. Don't get us into a mess.

25 MR. WALLACE: Okay. I'll be very careful.

GUELCHER - REDIRECT - WALLACE -

1 (Sidebar concluded.)

2 BY MR. WALLACE:

3 Q. Dr. Guelcher, I'm going to ask a very simple yes or no
4 question and I just want you to answer it yes or no without an
5 explanation.

6 Have you given any presentations to scientific peers on
7 the failure of vaginal mesh?

8 A. Have I given any? No.

9 Q. Well, let me ask, I'm going to give you your CV and ask
10 if I can refresh your recollection.

11 THE COURT: Yes, sir.

12 MR. THOMAS: I'll let him ask the question first.

13 BY MR. WALLACE:

14 Q. I'm going to direct you to page 18 of your CV, page 153.
15 I'd ask that you don't say anything else other than whether or
16 not you've given a presentation to scientific communities
17 about the failure of vaginal mesh.

18 MR. THOMAS: Your Honor, asked and answered. The
19 question is whether it refreshes his recollection.

20 THE COURT: I'll let him answer.

21 THE WITNESS: I'd like to explain my answer.

22 THE COURT: No.

23 THE WITNESS: It's --

24 THE COURT: No. Honestly, we're almost finished here
25 -- go ahead.

—GUELCHER - REDIRECT - WALLACE—

1 THE WITNESS: I'm trying to do this the right way.

2 BY MR. WALLACE:

3 Q. Can you just answer yes or no? Have you ever given a
4 presentation or gone or been invited to any conferences to
5 speak on that issue?

6 THE COURT: I overrule your objection. He may
7 impeach his own witness.

8 THE WITNESS: But there's a very simple 15-second
9 explanation.

10 THE COURT: I am telling you, if you don't answer
11 this question directly, you're excused.

12 THE WITNESS: No.

13 BY MR. WALLACE:

14 Q. You were asked some questions -- I've just got a couple
15 more questions. You were asked some questions about FTIR
16 tests and whether or not they could find degradation.

17 A. Yes.

18 Q. Are there limits to FTIR testing and whether or not
19 that's a valid way to find degradation?

20 A. FTIR probes, it measures the sample surface and also the
21 interior, so you're typically measuring the entire volume and
22 not specifically what happens at the surface.

23 THE COURT: So I bet that's a yes.

24 THE WITNESS: Yes.

25 BY MR. WALLACE:

—HELHAMMER - BY VIDEO—

1 Q. Have any of Mr. Thomas's questions changed your opinion
2 in this case?

3 A. No.

4 MR. WALLACE: Thank you.

5 THE COURT: All right. May the witness be excused
6 from the trial? Or do you want him --

7 MR. THOMAS: Yes, Your Honor.

8 MR. WALLACE: Yes, sir.

9 THE COURT: All right. Thank you very much, Doctor.
10 Call your next witness.

11 Doing all right, ladies and gentlemen? All right.

12 MR. WALLACE: We're going to play the video
13 deposition of Brigette Helhammer, Your Honor.

14 THE COURT: Ladies and gentlemen, the next testimony
15 you will be presented with is by way of video deposition. As
16 you've already heard from the lawyers, a deposition is sworn
17 testimony. This particular testimony is taken and is done so
18 under oath and you are to consider it as offered to you just
19 the same as if that witness was sitting here today live.
20 You're to give it no greater weight or no lesser weight
21 because it's on TV.

22 You may proceed.

23 MR. WALLACE: Thank you, Your Honor.

24 (The video testimony of Brigette Helhammer was
25 played.)

ROSENZWEIG - DIRECT - KUNTZ

1 MR. KUNTZ: Judge, that concludes the deposition of
2 Brigitte Helhammer.

3 THE COURT: All right. Call your next witness.

4 MR. COMBS: Judge, there will be a very short defense
5 cross examination.

6 THE COURT: Okay. Well, let's do that.

7 (The video testimony of Brigitte Helhammer
8 continued.)

9 MR. KUNTZ: Short redirect.

10 THE COURT: Redirect.

11 (The video testimony of Brigitte Helhammer
12 continued.)

13 THE COURT: All right. Thank you.

14 Ladies and gentlemen of the jury, that concludes the
15 videotaped testimony of this witness. You are to consider
16 that testimony the same way you would as if the witness were
17 here testifying. As to the technical quality of the video, I
18 want to assure you that the lighting technician has been hired
19 by Steven Spielberg and will not be available for later work.

20 Call your next witness.

21 MR. KUNTZ: Plaintiffs call Dr. Bruce Rosenzweig.

22 **BRUCE A. ROSENZWEIG**, called as a witness, having been first
23 duly sworn according to law, testified as follows:

24 DIRECT EXAMINATION OF BRUCE A. ROSENZWEIG BY MR. KUNTZ:

25 Q. Please state your name for the record.

-ROSENZWEIG - DIRECT - KUNTZ -

1 A. Bruce Alan Rosenzweig.

2 Q. And are you a physician?

3 A. Yes, I am.

4 Q. What kind of doctor are you?

5 A. My specialty is gynecology and my subspecialty is
6 urogynecology.

7 Q. Please describe to the jury your medical training and
8 experience.

9 A. I went to the University of Michigan for medical school.
10 After that I did a postgraduate residency program in
11 obstetrics and gynecology. Following that -- which is a four
12 year residency. I spent one year after that doing what's
13 called a pelvic surgery fellowship, which is an advanced
14 pelvic surgery. And then I did a two-year fellowship in
15 urogynecology.

16 Q. Are you licensed to practice medicine?

17 A. Yes, sir.

18 Q. What states?

19 A. I have an active license in the state of Illinois.

20 Q. What teaching positions have you held?

21 A. Currently I'm an assistant professor at in obstetrics and
22 gynecology at Rush University Medical Center.

23 Q. Have you published any articles related to the treatment
24 of stress urinary incontinence?

25 A. Yes, I have.

-ROSENZWEIG - DIRECT - KUNTZ -

1 Q. Okay. Have you published any articles related to the
2 pelvic floor?

3 A. Yes, I have.

4 Q. Have you presented lectures on stress urinary
5 incontinence?

6 A. Yes, I have.

7 Q. About how many lectures have you presented?

8 A. I've presented several hundred lectures, probably the
9 majority of those have to do with urinary incontinence or
10 pelvic floor.

11 Q. Please describe to the jury your current practice in
12 urogynecology and the treatment of stress urinary
13 incontinence.

14 A. Well, I see patients in the office two days a week and I
15 operate a day and a half a week, and then I have other
16 responsibilities.

17 Q. How many times do you perform surgery a week?

18 A. A day and a half, sir.

19 Q. Do you remove pelvic mesh products during your surgeries?

20 A. Yes, I do.

21 Q. And how many pelvic mesh products do you think you've
22 removed in your career?

23 A. Over 250.

24 Q. And how many of those products were sling products that
25 you've removed?

-ROSENZWEIG - DIRECT - KUNTZ -

1 A. Approximately 75 percent, or about 200.

2 Q. And how many of those sling products that you removed
3 were products made by Ethicon?

4 A. Probably about 40 to 50.

5 Q. And how about actual sling products by Ethicon that you
6 have removed from your patients?

7 A. That's about 40 or 50 Ethicon sling products.

8 Q. Do those include the TVT products?

9 A. That is correct.

10 Q. The TVT Retropubic?

11 A. That is correct.

12 Q. And the TVT-O?

13 A. That is correct.

14 Q. How do you know when you're removing them that they're
15 Ethicon products?

16 A. Well, a lot of times I have the operative report. It's
17 always good to see before you operate on a patient what
18 procedure they had, what kind of material they had. Also, the
19 TVT products are blue which makes it easier to see and
20 distinguish in the operating room.

21 MR. KUNTZ: May I approach the witness, Your Honor?

22 THE COURT: You may.

23 BY MR. KUNTZ:

24 Q. I'm going to hand you what's been marked exhibit 90003A.
25 Tell the jury what that document is, doctor?

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1 A. This is my curriculum vitae. It is kind of your calling
2 card, your resumé of the things that you've done throughout
3 your career.

4 Q. Okay. Does this accurately reflect the things that we
5 just discussed, your experience, your training and your
6 practice?

7 A. That is correct.

8 MR. KUNTZ: Your Honor, I would move to qualify Dr.
9 Rosenzweig as a witness and move to admit his CV.

10 THE COURT: Any voir dire?

11 MS. JONES: Not at this time, Your Honor.

12 THE COURT: Doctor, you may answer opinion questions
13 placed to you in your area of expertise.

14 THE WITNESS: Yes.

15 MR. KUNTZ: I apologize, Your Honor, but I'd also
16 move to admit his CV.

17 THE COURT: Is there objection?

18 MS. JONES: I have no objection, Your Honor.

19 THE COURT: It may be received.

20 (THE PLAINTIFFS' EXHIBIT WAS RECEIVED IN EVIDENCE.)

21 BY MR. KUNTZ:

22 Q. Dr. Rosenzweig, when did we first contact you to review
23 this case?

24 A. Approximately the fall of 2013.

25 Q. And did we ask you to form opinions about the TVT-O

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1 device?

2 A. That is correct.

3 Q. What materials have you reviewed in this case to form
4 your opinions?

5 A. I've reviewed the literature, I've reviewed internal
6 documents, and I've reviewed deposition testimony of medical
7 directors, scientists and also other Ethicon corporate
8 witnesses.

9 Q. How much have you charged for your time in Jo Huskey's
10 case?

11 A. Approximately 50 to \$70,000, that's at \$500 an hour for
12 reviewing materials.

13 Q. And are you charging for your time here to be at trial
14 here today?

15 A. That is correct. I'm charging \$5,000 a day to be here at
16 trial.

17 Q. And how do you determine that rate, Dr. Rosenzweig?

18 A. Well, I have a private practice; not only am I
19 responsible for paying my own salary, but my employees'
20 salary. I pay for the rent, their health insurance, other
21 overhead for my practice, and so that rate is to, to take care
22 of my time away from practice to compensate me for my time
23 away from my practice.

24 Q. How much time have you spent reviewing documents in this
25 case?

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1 A. Between 120 and 140 hours.

2 Q. Talk a little bit -- let me ask you this. Your practice
3 obviously involves treating patients for stress urinary
4 incontinence?

5 A. That is correct.

6 Q. We've heard a little bit about it, but what is stress
7 urinary incontinence?

8 A. Well, stress urinary incontinence is a medical condition
9 whereby a woman will actually lose her urine during activities
10 such as coughing, sneezing or other things that increase the
11 pressure inside the abdomen.

12 Q. Is it a life-threatening condition?

13 A. No, but it can be embarrassing. It can be also a social
14 or a hygienic problem.

15 Q. What percentage of stress urinary incidence is severe?

16 A. Well, it's been estimated only about 10 percent of stress
17 urinary incontinence is severe, and by severe we mean leaking
18 more than one time a day.

19 Q. And what are the different surgical options to treat
20 stress urinary incontinence?

21 A. There are three basic procedures. One is called the
22 Burch procedure, one is called the pubovaginal sling
23 procedure, and the final category is called the midurethral
24 sling procedure.

25 Q. I'm going to pull up a slide of the different SUI

ROSENZWEIG - DIRECT - KUNTZ

1 treatment options. If there's no objection, Your Honor.

2 MS. JONES: I have no objection to the use of the
3 demonstrative.

4 THE COURT: You may display.

5 BY MR. KUNTZ:

6 Q. Slide one. Dr. Rosenzweig, if you could kind of walk the
7 jury through the three different procedures that you have done
8 or that you recognize for the treatment of stress urinary
9 incontinence.

10 A. Yes. The first is called the Burch procedure. That is a
11 procedure that is done either with a telescope called a
12 laparoscope or through a small incision that's done above the
13 pubic bone. The pubic bone is basically the bone that your
14 belt buckle sits on.

15 You go into the area above the internal organs of the
16 abdomen. The abdomen is covered by, if you will, a cellophane
17 wrapping which protects the bowel and the other internal
18 organs from any kind of injury from rubbing together. So you
19 go down to that layer which is sitting right next to the
20 bladder, and two stitches are placed on each side of the
21 opening of the bladder, which is called the bladder neck, and
22 the area where the urethra, which is the tube that you pee out
23 of, comes out of the bladder. Those are brought up to a
24 strong ligament on the inside of the pubic bone, which is
25 called the Cooper's ligament, and the sutures are tied.

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1 The pubovaginal sling is an operation where a material,
2 usually it is something like a strip of fascia -- fascia is a
3 substance that is like a tendon or a ligament. It's made out
4 of collagen, so it is fairly strong. And this is placed
5 either through the vagina or through an incision at the level
6 of the opening of the bladder, which is called the bladder
7 neck, and brought up through the muscles that is called the
8 rectus muscle. That's your abdominal muscles that you try to
9 strengthen while doing sit-ups.

10 The final is the midurethral sling which is a technique
11 by which a piece of polypropylene in a tape-like fashion is
12 placed at the level of the midpart of the urethra and either
13 brought up above the pubic bone or out through the inner
14 thigh.

15 Q. Have you performed all three of these procedures?

16 A. Yes, I have.

17 Q. Have you performed the TVT-O procedure that's at issue in
18 this case?

19 A. Yes, I have.

20 Q. Have you performed the TVT procedure, the predecessor
21 product to the TVT-O?

22 A. That is correct.

23 Q. In total in your career how many surgical procedures of
24 all types combined to treat stress urinary incontinence have
25 you performed?

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1 A. Over 1600.

2 Q. Which surgery do you normally do or do you prefer for the
3 treatment of stress urinary incontinence?

4 A. I perform the Burch procedure.

5 Q. And how many Burch procedures have you performed?

6 A. Over 1200.

7 Q. How long has the Burch procedure been around?

8 A. Since about the mid Sixties.

9 Q. Is it still recognized as a standard of care?

10 A. That is correct.

11 Q. Is it still recognized by AGOS, the AUA and other
12 physician society groups?

13 A. That is correct.

14 Q. And you've explained the procedure to us a little bit.
15 How big is the incision for a Burch procedure?

16 A. Well, normally if I'm just doing this as a standalone
17 procedure, I can get by with a fairly small incision, maybe
18 four inches. If I'm doing it with a hysterectomy or another
19 surgical procedure, the incision might be a little bit bigger.
20 Obviously there might be some anatomical variation where the
21 patient might be a little bit larger, then I would have to
22 like make a slightly bigger incision.

23 Q. How long do you patients normally stay in the hospital
24 after a Burch procedure?

25 A. Usually overnight, occasionally two days.

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1 Q. Is there literature of a course where patients stay
2 longer after Burch procedures?

3 A. Yes. But in my practice I don't see the necessity to do
4 that.

5 Q. Is there any mesh involved in a Burch procedure?

6 A. No. It's using sutures instead of a woven mesh.

7 Q. In all of the literature you've reviewed, we're going to
8 discuss some of it, between the Burch and the TVT-O procedure,
9 were they both effective at the same rates?

10 A. That is correct.

11 Q. Is there literature that shows that the two procedures
12 are equivalent?

13 A. Yes. There have been approximately three long-term,
14 meaning five year, randomized control trials. A randomized
15 control trial means that patients are randomly assigned to get
16 one procedure or the other, and then the patient has the
17 procedure, and then they're followed up for a period of time,
18 and in these studies it's up to five years. And there was
19 found to be no difference in the success rate between the
20 procedures.

21 Q. In your experience, in your practice and the literature
22 you've reviewed, do you see long-term complications with
23 Burch?

24 A. I have not experienced a significant number of long-term
25 complications. I rarely see any long-term complications from

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1 my Burch procedure.

2 Q. What do you define as long-term?

3 A. Well, short-term is following up someone for one to two
4 years, long-term, five to ten years is what is standardly
5 considered short-term and long-term.

6 Q. How long do you consider post operative pain to be?

7 A. Well, normally when a patient comes in to have a surgical
8 procedure, they understand that they're going to have some
9 pain right after surgery from making the cut or we're doing
10 some procedure on an organ, there's going to be some
11 discomfort afterwards as the area that was operated on heals.
12 Normally it can be as short as a few weeks or as long as four
13 to six weeks.

14 Q. And is post operative pain something you see with every
15 operation?

16 A. That is correct.

17 Q. And is that very different than long-term chronic pain?

18 A. That is correct.

19 Q. In your practice doing I think you said over a thousand
20 Burch procedures, you've never seen a patient with long-term
21 pain?

22 A. I can't remember any. There have probably been less than
23 a handful.

24 Q. You've testified that you've used both TVT Retropubic and
25 TVT Obturator products, is that correct?

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1 A. That is correct.

2 Q. Explain to the jury a little bit -- first tell them what
3 the TVT Retropubic device is and when it came out.

4 A. Yes. The Retropubic TVT, as we talked before, comes with
5 the piece of tape, the polypropylene, it's placed through the
6 vagina and the ends come out above the pubic bone through the
7 abdominal wall, through the incision in the skin. This was
8 created in the mid Nineties.

9 And the other technique is known as the trans -- should
10 I move on to the transobturator?

11 Q. Right.

12 A. The transobturator technique is the other technique, what
13 we're talking about in this case, are where again an incision
14 is made in the vagina and the polypropylene tape is brought
15 out through the inner thigh.

16 Q. Before you ever implanted slings, did you have a concern
17 about them?

18 A. That is correct.

19 Q. Did you discuss those concerns with anybody?

20 THE COURT: Excuse me.

21 MS. JONES: I'm sorry. I apologize, Counsel. I'm
22 having a hard time when you back away.

23 BY MR. KUNTZ:

24 Q. Prior to the time you ever implanted a sling, did you
25 have concerns about them?

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1 MS. JONES: Objection, Your Honor.

2 THE COURT: Sustained.

3 BY MR. KUNTZ:

4 Q. When's the first time that you implanted --

5 THE COURT: Would you turn his microphone up a little
6 bit?

7 THE DEPUTY CLERK: I can't.

8 THE COURT: Would you speak a little louder? I'm
9 having trouble too, I thought it was just my age.

10 MR. KUNTZ: I will, Your Honor. I apologize.

11 BY MR. KUNTZ:

12 Q. When's the first time that you implanted a TVT?

13 A. In 2003.

14 Q. When is the first time that you implanted the TVT-O
15 that's at issue in this case?

16 A. Well, I had the opportunity to go to Belgium --

17 MS. JONES: Objection, Your Honor. Non-responsive.

18 THE COURT: Sustained. If you'll just answer his
19 question.

20 THE WITNESS: Yes. In October of 2004.

21 THE COURT: There you go.

22 BY MR. KUNTZ:

23 Q. Were you invited by Ethicon to attend one of their
24 training sessions?

25 A. That is correct.

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1 Q. And when was that?

2 A. October of 2004.

3 Q. And where did that training take place?

4 A. In Liege, Belgium.

5 Q. And did that training with the TVT-O take place with Dr.
6 de Leval, the inventor of the product?

7 A. That is correct.

8 Q. And you were invited by Ethicon and they paid for you to
9 go over to Belgium and train with Dr. de Leval?

10 A. That is also correct.

11 Q. Tell us a little bit about that training class over in
12 Belgium.

13 A. Well, it was a three-day course. The first day was in a
14 classroom where we had didactic lectures. The second day we
15 spent in a cadaver laboratory where we got to do dissections
16 to show the area where the tape was going to go anatomically,
17 and also on a cadaver actually place the tape. And then the
18 third day we spent in the operating room with Dr. de Leval and
19 I had the opportunity of placing the tape in two live
20 patients.

21 THE COURT: All right. It's five o'clock. I'm quite
22 certain this witness will take more than just a few more
23 minutes. We're going to recess for the day.

24 Thank you, Doctor, you may step down.

25 Ladies and gentlemen of the jury, that concludes the

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1 testimony for today. We will -- you can go ahead, Doctor.

2 We'll start again in the morning right at 9:00
3 o'clock. I appreciate your promptness. We'll begin on time.
4 I missed it by ten minutes this morning, I'm not going to miss
5 it tomorrow.

6 Very important. Don't watch TV, local news, don't
7 read the newspaper, local newspaper. You can read the New
8 York Times or something like that. You can watch the national
9 news. If you want to stay happy, just don't watch the news,
10 it's depressing.

11 You're not to listen to, read anything about, see
12 anything, do any research about, use any social media, talk to
13 anyone about, answer any questions about this case.
14 Everything that you're allowed to do about this case you're
15 allowed to do right in here. Don't discuss it with anyone or
16 among yourselves. Have a very pleasant evening and I'll see
17 you right at 9:00 o'clock.

18 You're excused.

19 Counsel, do you want to stay a minute?

20 (The Jury left the courtroom at 5:02 p.m.)

21 THE COURT: Anything you need me for?

22 I appreciate the nice professional relationship
23 between counsel and the way this is going. Keep it up. See
24 you tomorrow morning.

25 MR. KUNTZ: Thank you, Your Honor.

1 (A recess was taken at 5:03 p.m.)

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3

4 **REPORTERS' CERTIFICATE**

5

6 **Carol Farrell, CRR, RMR, CCP, RPR**, Official Court
7 Reporter of the United States District Court for the Southern
8 District of West Virginia, and **Anthony Rolland, CRR, RMR, RPR**,
9 do hereby certify that the foregoing is a true and accurate
10 transcript, to the best of our ability, of the proceedings as
11 taken stenographically by and before us at the time, place,
12 and on the date hereinbefore set forth.

13

14

15 /S/ **Carol Farrell, CRR, RMR, CCP, RPR**

08/25/2014

16

Court Reporter

Date

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/S/ **Anthony Rolland, CRR, RMR, RPR**

08/25/2014

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Court Reporter

Date

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